



# Guidance for the Reregistration of Pesticide Products Containing DIAZINON as the Active Ingredient



U.S. Environmental Protection Agency  
Region V, Library  
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Chicago, Illinois 60604

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REGISTRATION STANDARD  
FOR THE  
REREGISTRATION OF PESTICIDE PRODUCTS  
CONTAINING  
DIAZINON  
[057801]  
AS THE ACTIVE INGREDIENT

[CASE NUMBER-0238]  
[CAS NUMBER 333-41-5]

DECEMBER 1988

ENVIRONMENTAL PROTECTION AGENCY  
OFFICE OF PESTICIDE PROGRAMS  
WASHINGTON, D.C. 20460

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## GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	An acceptable daily intake of pesticide residue based on a complete data base.
a.i.	Active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
DESHC	Division of Endangered Species & Habitat Conservation
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
GC	Gas Chromatography
GLC	Gas Liquid Chromatography
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air, or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral or dermal). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
ppm	Parts per million
RfD	Reference Dose: An estimate of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The reference dose is a replacement term for the term acceptable daily intake (ADI).
TMRC	Theoretical Maximum Residue Contribution: An estimate of dietary exposure obtained by multiplying residue tolerance levels for a given pesticide by the average daily per capita food consumption figure, then adding the exposure figure for each crop. The TMRC is usually expressed in terms of mg/kg of food.

## I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request,<sup>1</sup> focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the

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<sup>1</sup>The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket, Field Operations Division, telephone number (703) 557-2805 or by writing EPA, Public Information Branch, FOD, 401 M Street, S.W., Washington, DC 20460.

provisions of this Registration Standard to end use products if necessary to protect man and the environment.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submittal of data in support of product registration;
2. Modification of product labels;
3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;
4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;
5. Modification of uses or formulation types; or
6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

## II. CHEMICAL COVERED BY THIS STANDARD

### A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common name: Diazinon  
Chemical name: O,O-Diethyl O-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate.  
Other Chemical Nomenclature: O,O-Diethyl O-(2-isopropyl-6-methyl-pyrimidin-4-yl) phosphorothioate.  
CAS Number: 333-41-5  
ENT Number: 19507  
OPP (Shaughnessy) Number: 057801  
Empirical Formula:  $C_{12}H_{21}N_2O_3PS$   
Molecular Weight: 304.3  
Trade names: Spectracide, D.Z.N., Knox-Out, Alfa-tox, Saroles, Basudin, AG-500.

#### Description of physical characteristics of chemical <sup>2</sup>

Color: amber and brown  
Physical State: liquid  
Odor: mild, sweet, aromatic  
Melting Point: liquid at 25°C  
Boiling Point: 83-84°C at 0.002 mm Hg  
Specific Gravity: 1.12 g/ml at 20°C  
Solubility: 60 ppm in water at 25°C and 40 ppm in water at 20°C .  
Vapor Pressure:  $1.4 \times 10^{-4}$  mm at 20°C  
Partition Coefficient: pK= 4.4 at 20°C

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<sup>2</sup> Physical/chemical properties are for the technical products, Note: Diazinon technical products are marketed as "stabilized technicals"; therefore, these products are actually formulation intermediates (manufacturing use products).

B. USE PROFILE

Type of Pesticide: Insecticide

Pests Controlled: soil insects, such as cutworms, wireworms, and maggots. Pests affecting fruits, vegetables, tobacco, forage, field crops, range, pasture grasslands, and ornamentals. Many household insects including cockroaches. Several turf pests including white grubs and chinch bugs. Seed treatment and fly control. Fleas and ticks on domestic pets.

C. REGISTERED USES:

[Use pattern groupings; for specific crops and use patterns refer to the EPA Compendium of Acceptable Uses]

<u>TERRESTRIAL</u> <u>FOOD CROPS</u>	<u>TERRESTRIAL</u> <u>NON-FOOD CROPS</u>	<u>GREENHOUSE</u> <u>FOOD CROPS</u>	<u>GREENHOUSE</u> <u>NON-FOOD CROPS</u>
<u>Vegetable Groups</u> root & tuber bulb, leafy, brassica leafy, legume, legume foliage, cucurbits.	Tobacco, ornamental plants trees and turf.  NON CROP, WIDE AREA, & GENERAL OUTDOOR TREATMENT: barrier strips, ditch banks, non- crop areas, roadsides and	Cabbage, cantaloupe, cauliflower, cucumber, egg plant, mushroom houses, summer squash, watermelons, zucchini.	Ornamental Plants.
<u>Fruit Groups</u> citrus, pome, stone, small fruit and berries.			

Tree Nut Group,                wastelands.  
Cereal Grains  
Group, Forage and  
Fodder Grasses,  
Non-Grass  
Animal Feed

INDOOR

Pets and  
Domestic  
Animals.

Animals and  
Their Man-made  
Premises.

Household(domes-  
tic dwellings  
indoor.

Commercial and  
Industrial Uses.

Food/Feed  
Processing  
Facilities.

DOMESTIC OUTDOOR

Households;  
domestic  
dwellings.

Annual Usage: 10 million pounds active ingredient  
(1985 data).

Predominant Use(s)<sup>3</sup>: Agricultural market 40% and Home  
and Garden uses 20%. Professional app-  
lication such as golf courses represented 40%.

Mode of Activity: Cholinesterase inhibition.

Formulation Types Registered: Dusts, emulsifiable concen-  
trates, granules, impregnated materials,  
liquids, microencapsulated, pressurized  
sprays, soluble concentrates, wettable  
powders.

Method(s) of Application: Aerosols, sprays, pet collars,  
insect tape, ear tags, ground blast, aerial,  
and soil incorporated.

#### C. REGISTRATION HISTORY

Year of Initial Registration: 1956

Basic Producers: Ciba-Geigy, Trans Chemic Industries, Inc.,  
and Makhteshim Agan (America) Inc.

End-use Registrants: 411

Number of Registrations: 1,169 Section 3  
206 24-C

In January 1986, The Agency initiated a Special Review of diazinon's uses on golf courses and sod farms based on acute toxicity risks to avian species. This concern was based on available laboratory data on acute and dietary toxicity, exposure data, field studies, and reported bird kill incidents associated with these two sites of diazinon application. After assessing these risks and comparing them to the benefits afforded by diazinon on these sites, the Agency concluded on September 24, 1986 that the risks by exceeding the benefits were unreasonable. The Agency cancelled the registrations for these two use patterns.

This Special Review decision has been the subject of two completed legal appeals and is currently the subject of a third legal appeal in progress. During this current appeal, the golf course and sod farm uses remain cancelled.

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<sup>3</sup> Precent usage based on use information developed by EPA 1985. Precent usage excluding the cancelled uses are not currently avialable.



### Data-Call-In Notices Issued

The Agency has issued the following 3(c)(2)(B)  
Data-Call-In (DCI) Notices:

<u>Date Issued</u>	<u>Data Required</u>	<u>Due Date</u>	<u>Status</u>
2-18-83	Teratogenicity (one species)	5/85	See section III-B
7-24-84	Groundwater [hydrolysis, photodegradation on soil and in water, aerobic soil, ana- erobic soil and aquatic metabolism, mobility, (field) dissipation soil] Product chemistry.	6/87*	See section III-D
5-30-86	Reentry [foliar dissipation, soil dissipation, dermal exposure, inhalation exposure]	12/87	See section III-D
5-01-87	Comprehensive [environmental fate, fish and wildlife, product chemistry-mup's and technical's only, residue chemistry, and toxicity]	12/91*	Under review

\* Due date of final submission.

### III. AGENCY ASSESSMENT

The Agency has reviewed all data in Agency files as of May 1987 supporting the registration of diazinon. Product chemistry data submitted in response to the 1987 DCI on the registered manufacturing use products and plant phytotoxicity data have also been reviewed. Other data required by the 1987 DCI have been received and are currently under review (for specific data under review refer to data tables in Appendix I). This section discusses the Agency's scientific findings and conclusions based on these data.

#### A. SUMMARY

Currently registered manufacturing use products have been determined to be substantially similar but not identical. The toxicological similarity between the manufacturing use products cannot be ascertained. The Agency is requiring toxicity data on each manufacturing use product to determine toxicological similarity.

Available data on manufacturing use products characterize diazinon as moderately toxic on an acute oral basis and mildly toxic on an acute dermal and inhalation basis. Diazinon did not elicit dermal or eye irritation when tested. Diazinon elicited positive responses for dermal sensitization in about 10% of the human volunteers tested.

Diazinon is not oncogenic in the Fisher F344 rat or in the B6C3F1 mouse.

Diazinon does not induce developmental toxicity in rats at dose levels up and including 100 mg/kg/day (highest dose tested). Decreased food consumption and body weight gain in the treated dams were observed at 100 mg/kg/day.

Diazinon does not induce developmental toxicity in rabbits at dose levels up and including 100 mg/kg/day (highest dose tested). Significant maternal toxicity was observed at 100 mg/kg/day.

Based on acceptable laboratory data, technical diazinon is characterized as very highly toxic to waterfowl on an acute oral basis, with an LD<sub>50</sub> of 6.38 mg/kg for mallard ducks. Avian dietary studies characterized diazinon as highly toxic to upland game birds with a dietary LC<sub>50</sub> of 245 ppm for bobwhite quail. Supplemental data characterize diazinon as very highly toxic to waterfowl with a dietary LC<sub>50</sub> of less than 47 ppm for mallard ducks.

Granular end-use formulations of diazinon are characterized as very highly toxic to waterfowl, upland game birds and songbirds on an acute oral and dietary basis.

Technical diazinon and its end-use formulations are characterized as very highly toxic to aquatic organisms. It is considered highly toxic to non-target insects.

Diazinon degrades rapidly under aerobic, anaerobic, aquatic anaerobic and sterile soil conditions.

Microbial degradation appears to be the major pathway for the degradation of diazinon. The most probable mechanism responsible for degradation under sterile and anaerobic soil conditions appears to be chemical hydrolysis in acidic soils. Supplemental hydrolysis data indicate the diazinon is stable with respect to hydrolysis at pH 7 and 9 but hydrolyzes in non-sterile water with pH 5.

The major soil degradate is oxypyrimidine. Oxypyrimidine is more persistent than diazinon under aerobic, sterile, and anaerobic aquatic soil conditions.

Diazinon with a 4 day EC50 of 4.14 mg/L and a 7 day EC50 of 3.7 mg/L may be characterized as moderately toxic to freshwater green alga. Diazinon caused greater than 25% detrimental effect in plant vigor in tomatoes, cucumbers, onions, lettuce, and carrots. Diazinon caused greater than 25% detrimental effect in seed germination in oats, tomatoes, and carrots. No detrimental effect was seen for seedling emergence.

## B. HEALTH EFFECTS ASSESSMENT

### 1. Acute Toxicity

Available data on manufacturing use products characterize diazinon as moderately toxic on an acute oral basis (LD50=618 mg/kg, toxicity category III) and mildly toxic (toxicity category III) on an acute dermal and inhalation basis (LD50 >2,000 mg/kg and LC50= 3.5 mg/L respectively). Technical diazinon did not elicit dermal or eye irritation when tested (toxicity category IV). Technical diazinon elicited positive responses for dermal sensitization in about 10% of the human volunteers tested.

There are no acceptable acute delayed neurotoxicity studies available. Since diazinon is an organophosphate insecticide it must be tested for delayed neurotoxicity.

## 2. Subchronic Toxicity

The Agency does not have any acceptable subchronic data to support registration of products containing diazinon. A full battery of subchronic testing is required.

## 3. Oncogenicity

Acceptable oncogenicity studies have been performed using diazinon in the Fisher F344 rat and in the B6C3F1 mouse. These studies are discussed below:

### a. NCI/NTP Diazinon Oncogenicity Study in the Fisher F344 Rat

In this study, diazinon (purity 98%) was administered to F344 rats via the diet at dosage levels of 400 and 800 ppm (approximately 20 and 40 mg/kg/day respectively) for 103 weeks followed by a 2 week observation period. Dose levels were selected following a subchronic range-finding study which showed body weight loss at 1600 ppm (80 mg/kg/day) (in females) and some deaths at 3200 ppm (160 mg/kg/day).

NCI/NTP concluded that histopathologic examination provided no convincing evidence for the carcinogenicity of diazinon in F344 rats under the conditions of this bioassay.

The Agency agrees with NCI/NTP that diazinon is not carcinogenic in Fisher F344 rats.

### b. NCI/NTP Diazinon Oncogenicity Study in the B6C3F1 Mouse

In this study, diazinon (purity 98%) was administered via the diet to B6C3F1 mice. There were 25 of each sex for the concurrent control group and 50 of each sex for the groups dosed with 100 and 200 ppm (approximately 15 and 30 mg/kg/day respectively). The mice were dosed with diazinon for 103 weeks. These dose levels were selected on the basis of a preliminary subchronic study which showed that 800 ppm (approximately 120 mg/kg/day) resulted in weight loss, in females, and 1600 ppm (approximately 240 mg/kg/day) resulted in deaths in males and females.

The study indicated that diazinon was not associated with increased incidence of neoplasms. It was concluded that under the conditions of this bioassay diazinon was not oncogenic in mice at dose levels up and including 200 ppm (approximately 30 mg/kg/day).

## 4. Metabolism

The Agency does not have any acceptable metabolism data to support registration of products containing diazinon. Metabolism data are required.

## 5. Teratogenicity

Acceptable teratogenicity studies have been performed using diazinon in the New Zealand strain rabbit and in the Sprague-Dawley rat. These studies are discussed below:

### a. Teratogenicity in Rabbits

In this study, New Zealand strain rabbit does were given, single oral doses of diazinon via gavage on days 6 through 18 of gestation. Doses employed were 0 (control), 7, 25, and 100 mg/kg/day. Significant maternal toxicity was observed in the highest dose group, 100 mg/kg/day. There were no indications of developmental toxicity in any of the dose levels studied.

The Agency concluded that diazinon does not induce developmental toxicity in rabbits at dose levels up to and including 100 mg/kg/day.

### b. Teratogenicity in Rats

In this study, Sprague-Dawley strain rat dams were given single daily doses of diazinon, via oral gavage, on days 6 through 15 of gestation. Doses employed were 0 (control), 10, 20, and 100 mg/kg/day. On day 20 dams were sacrificed and the pups assessed for signs of developmental toxicity. Signs of maternal toxicity in the dams included decreased food consumption and body weight gains. Developmental toxicity was not observed in this study at dose levels up to and including 100 mg/kg/day.

## 6. Reproduction

The Agency does not have an acceptable multi-generation reproduction study to support the registration of products containing diazinon. A study in the rat is required.

## 7. Mutagenicity

Diazinon was evaluated along with 17 other pesticides for mutagenic or genotoxic effects in the following assays:

- o Reverse mutation in Salmonella typhimurium strains TA1535, TA1537, TA1538, TA98, and TA100 and in Escherichia coli WP2 uvrA.
- o Induction of mitotic recombination in the yeast Saccharomyces cerevisiae D3.
- o Relative toxicity assays in DNA repair-proficient and deficient strains of E. coli (strains W3110 and P3478, respectively) and of Bacillus subtilis (strains H17 and M45, respectively).
- o Unscheduled DNA synthesis in human fibroblasts (WI-38 cells).

The Agency concluded that diazinon was not mutagenic under the conditions of these assays. Diazinon was, however, reported in the literature to be positive in a sister chromatid exchange assay in mudminnows.

The Agency is requiring that a structural chromosome aberration study (ie., a mouse micronucleus assay) and additional sister chromatid exchange assays using both in vivo and in vitro (with and without metabolic activation) be submitted.

The Agency is also requiring a summary table of all readily available studies conducted on diazinon for mutagenicity and genotoxic effects including literature references.

## C. ECOLOGICAL EFFECTS ASSESSMENT

### 1. Avian Species

#### a. Manufacturing Use Formulations:

Based on acceptable laboratory data, diazinon is characterized as very highly toxic to waterfowl on an acute oral basis, with an LD50 of 6.38 mg/kg for mallard ducks. Avian dietary studies characterized diazinon as highly toxic to upland game birds with a dietary LC50 of 245 ppm for bobwhite quail.

Supplemental data characterize diazinon as very highly toxic to waterfowl with a dietary LC50 of less than 47 ppm for mallard ducks. All birds died at the lowest test level. A new dietary study in mallard is required to determine the actual LC50 value.

b. End Use Formulations:

Based on acceptable laboratory data, the following diazinon formulations were characterized for acute oral toxicity;

<u>Avian Species</u>	<u>Formulation Type</u>	<u>Percent a.i.</u>	<u>LD<sub>50</sub> (mg ai/kg)</u>	<u>Toxicity Characterization</u>
House Sparrow	Granular	14	2.5	Very highly toxic
Redwinged Blackbird	Granular	14	1.8	Very highly toxic
Bobwhite Quail	Granular	14	8.0	Very highly toxic
Bobwhite Quail	Microencapsulated	23	108.5	Highly toxic

A dietary LC<sub>50</sub> study was conducted on Japanese quail using a 48% a.i. emulsifiable concentrate formulation. Results of this study characterized this formulation as highly toxic, with a dietary LC<sub>50</sub> of 101 ppm for this species of upland game bird. Avian dietary studies are required on songbirds (preferably brown-headed cowbird) and on waterfowl (preferably the mallard duck).

2. Aquatic Organisms

a. Manufacturing Use Formulations:

Based on acceptable laboratory data, diazinon was characterized for acute toxicity in the following aquatic organisms;

<u>Aquatic Species</u>	<u>Percent ai</u>	<u>LC<sub>50</sub> (ug/L)</u>	<u>Toxicity Characterized</u>
<u>Warmwater Fish:</u>			
Bluegill sunfish	92	168	Highly Toxic
Bluegill sunfish	92	460	Highly Toxic
Bluegill sunfish	91	136	Highly Toxic
<u>Coldwater Fish:</u>			
Rainbow Trout	89	90	Very highly toxic
Rainbow Trout	91	400	Highly toxic
Lake Trout	92	602	Highly toxic
Cutthroat Trout	92	1700	Moderately toxic
<u>Freshwater Invertebrates:</u>			
<u>Daphnia magna</u>	89	0.96	Very highly toxic
<u>Daphnia pulex</u>	89	0.8	Very highly toxic
<u>Gammarus fasciatus</u>	89	0.2	Very highly toxic
<u>Pteronarcys</u>	89	2.5	Very highly toxic
<u>Simocephalus</u>	89	1.4	Very highly toxic

Estuarine Organisms:

Sheepshead Minnow >89 1400 Moderately toxic

b. End Use Formulations

Based on acceptable laboratory data, the following diazinon formulation was characterized for acute toxicity;

<u>Aquatic Species</u>	<u>Percent ai</u>	<u>Formulation Type</u>	<u>LC<sub>50</sub> (ug/L)</u>	<u>Toxicity Characterized</u>
Warmwater Fish:				
Bluegill sunfish	23	microencap-sulated	512	Highly toxic
Coldwater Fish:				
Rainbow Trout	23	microencap-sulated	635	Highly toxic
Freshwater Invertebrate:				
<u>Daphnia magna</u>	23	microencap-sulated	0.522	Very highly toxic

3. Nontarget Insects

a. Pollinators

1. Manufacturing Use Formulations:

Based on the following acceptable laboratory data, there are sufficient data to characterize diazinon as highly toxic to honey bees (Apis mellifera). No additional data are required.

<u>Species Tested</u>	<u>LD50 (ug/bee)</u>	<u>Method of Testing</u>
Honey Bees	0.372	Contact LD50
Honey Bees	0.22	Contact LD50
Honey Bees	0.20	Oral LD50

2. End Use Formulations:

Based on acceptable laboratory data, two formulations of diazinon (40% wettable powder and 16% emulsifiable concentrate) were characterized as highly toxic through residual contact, feeding, direct contact and fumigation. No additional data are required.

b. Nontarget Soil and Surface Invertebrates

Based on acceptable data, two formulations of diazinon (25% and 50% wettable powder) were characterized as highly toxic to predaceous mites, parasitic wasps, and predaceous beetles, when used at standard field rates.



#### 4. Non-Target Area Phytotoxicity

##### a. Vegetative Vigor

Tier I non-target phytotoxicity studies were conducted to determine the effects of diazinon technical applied at the maximum rate of 10 lb ai/A, on the vegetative vigor of soybean, lettuce, carrot, tomato, cucumber, cabbage,, oat, ryegrass, corn, and onion. A single treatment of diazinon was applied. Treatment with diazinon resulted in a 25% or greater detrimental effect on vegetative vigor, as measured in plant height, on onion, cucumber, and tomato. Tier II testing is required in tomato, onion, lettuce, and carrot.

##### b. Seed Germination/Seedling Emergence

Tier I non-target phytotoxicity studies were conducted to determine the effects of diazinon technical on the seed germination and seedling emergence and subsequent early growth of soybean, lettuce, carrot, tomato, cucumber, cabbage, oat, ryegrass corn, and onion. In the seed germination study, ten seeds of each crop were placed in a plastic petri plate containing two pieces of Whatman #3 filter paper. Seven milliliters of a 30 ppm diazinon solution was added to each plate and the radicle length was measured. Treatment resulted in a 26, 27, and 43% decrease in radicle (embryonic root of a seedling) length in oat, tomato, and carrot seeds respectively.

A greater than 25% detrimental effect level was observed in oat, tomato, and carrot, based on effect on radicle length, in the seed germination study. Tier II testing is required in tomato, carrot, and oat.

In the seedling emergence study, a plexiglass template was used to uniformly plant ten seeds of each crop group in plastic pots. Diazinon was applied at the rate of 10 lb ai/A. Seedling height, percentage of seedling emerged, and phytotoxicity ratings were recorded 7, 14, and 20 days after treatment. Treatment resulted in no observable phytotoxic effects on any of the crops treated. Onion was the most sensitive crop tested with a mean phytotoxicity rating of 0.4 at day 20. The percent effect on the percentage of seedlings emerged at day 20 ranged from a 6% increase in soybean to an 5% decrease in onion. The percent effect seedling height at day 20 ranged from a 6% increase in oat to an 18% decrease in onion.

Detrimental effects were < 25% for seedling emergence, no additional testing is required.

### c. Aquatic Plant Growth

Technical diazinon was characterized as moderately toxic to freshwater green alga (Selenastrum capricornutum) with a 4-day EC50 of 4.14 mg/L (or 4.14 ppm) and a 7-day EC50 of 3.7 mg/L (or 3.7 ppm).

Diazinon when applied to turf at a maximum application rate of 17.1 lb ai/A (assuming 10 acres treated with a 2% runoff into a large 1 acre pond 0.5 feet deep) would result in a EEC of 2.5 ppm. The EEC does not exceed the 4 day or 7 day EC50 values for freshwater green algae.

Diazinon when applied to cranberries at the recommended application rate of 3.0 lb ai/A (assuming direct application to water 0.5 feet deep) would result in a EEC of 2.2 ppm. The EEC does not exceed the EC 50 value for freshwater green algae. No further testing is required.

## ECOLOGICAL RISK ASSESSMENT

### Avian Hazard

Diazinon's highest application rates are generally on citrus and vegetables (e.g., beans, beets, carrots, cabbage, radishes, turnips, corn, lettuce, peas, and tomatoes) with maximum rates up to 10 lb ai/A. Orchard crops (e.g., almonds, apples, pears) have maximum rates up to 6 lb ai/A. Grass sites have rates as high as 11 lb ai/A.

### Lawns, Parks, and other Grassy Sites

Avian risk that were identified for diazinon use on sod farms and golf courses appear to be substantially similar to avian risks when diazinon is used on other grassy sites such as home lawns, athletic fields, parks, etc. Bird exposure to residues of diazinon at these sites is also expected to occur.

Residue data on turf grass show average residue values per unit dose to be 53 ppm per application of 1 lb active ingredient followed by irrigation with 0.25 inches of water. A typical application rate of 4 lb ai/A would result in residues estimated at 212 ppm, which exceeds 1/5 the avian subacute dietary LC50 value.

A record of at least 50 bird kill incidents on grassy sites such as lawns and parks supports the concern that hazardous exposure regularly and routinely occurs. In total, over 80 bird kill incidents associated with diazinon have been reported to the Agency.

## Agricultural and Other Sites

### A. Feeding

Avian dietary exposure to diazinon occurs when birds feed on grass, roots, seeds, nuts, grains, fruits, and/or the invertebrates at the site of application. The average residue per unit dose is 33 ppm. A typical application rate of 6 lb ai/A would result in residues estimated at 198 ppm, which exceeds 1/5 the avian subacute dietary LC50 value. Dermal exposure to diazinon residues may also occur as they feed.

### B. Exposure in rainwater or irrigation puddles

Exposure to high concentrations of diazinon in water may also occur. Rain or irrigation (watering in) after diazinon application may result in the formation of pools of contaminated water (puddling) which poses an additional hazard to birds. Irrigation is recommended by the label for control of certain soil inhibiting pests. If the water is not immediately absorbed by the soil, puddles with high concentration of diazinon may form.

Bird kills from diazinon applications have been associated with irrigation and puddling. The Agency is concerned that even if applicators comply with the label directions, diazinon may still pose a hazard, because of the puddling effects.

### C. Ingestion of diazinon granules

In addition to the potential hazard from the exposure to residues on food items, birds may accidentally ingest granules because the granules may be mistaken for dietary grit. Diazinon granules are within the size range of grit for birds, and ingestion of only a few granules has been shown to be lethal to certain bird species. Diazinon granules are very highly toxic to birds: one granule of a 14.3% ai end-use product killed 40% of the test House Sparrows and 5 granules killed 100% of the test Red-winged Blackbirds.

Because only a few granules are needed to kill birds, residues in terms of number of granules would exceed 1/5 the LC50 under all application rates and practices.

Over 80 bird kill incidents associated with use to diazinon have been reported to the Agency. The record of kills, which includes application made by trained pesticide applicators, includes grass sites, orchards, and other agricultural sites. The kills are reported from States throughout the United States and occur throughout the year. Waterfowl were frequently involved but 23 species in total have been reported as killed as a result of exposure to diazinon.

## Aquatic Hazard

The Agency has reviewed valid aquatic studies on diazinon and some of its formulations. These studies characterize diazinon as moderately to very highly toxic to fish and highly toxic to aquatic invertebrates.

The Agency is concerned about the potential hazard of diazinon to aquatic organisms. Eight fish kills that implicate diazinon have been reported to the Agency. In most situations misuse appears to have occurred. In a few instances diazinon residues were found in the fish samples analyzed. The reported fish kills include a loss of 1,150 fish in Westwood, Pennsylvania; loss of 50 fish in Chester County, Pennsylvania; loss of 1,210 fish in Honolulu, Hawaii; loss of over 100 Cutthroat Trout in the Hood River, Oregon; loss of over 200 Rainbow Trout in Milton-Freewater, Oregon; loss of 35,000 suckers and sticklebacks in Sonia County, Michigan; loss of 20-25 fish in Sacramento, California; and a non-quantified loss of fish in Grove, Oklahoma.

Drift and/or runoff from application to agricultural and home sites may pose a hazard to aquatic organisms. Additional data are required to assess these potential hazards to aquatic organisms.

## Endangered Species

Due to diazinon's demonstrated toxicity to nontarget species and its intended use patterns, diazinon has been identified by the Division of Endangered Species and Habitat Conservation (DESHC), U.S. Fish and Wildlife Service (FWS), as being likely to jeopardize the continued existence of certain endangered species when used on range and pastureland, grain crops, soybeans, and sorghum.

In addition to the sites previously discussed, diazinon was identified by DESHC, U.S. Fish and Wildlife Service, as jeopardizing the continued existence of the following species: Mohave tui chub (Cial bicolor mohavenis) and the Hawaiian goose (Neoschen (= Branta) sandvicensis) when used on golf courses and sod farms.

Other species, listed below, were identified by DESHC as being adversely affected<sup>4</sup> by diazinon's golf and sod farms uses:

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<sup>4</sup> "Adversely affected" - as defined by the Division of Endangered Species and Habitat Conservation, FWS, means that some individuals may be killed but the species survival is not at stake.

Brown pelican (Pelecanus occidentalis)  
Alabama Beach Mouse (Peromyscus polionotus ammobates)  
Oregon Silverspot butterfly (Speryeria zerene hippolyta)  
June Sucker (Chasmistes liorus)  
San Francisco Garter snake (Thamnophis sirtallis  
tetrataenia)

For all other registered uses of diazinon that may affect federally listed endangered species the Agency will formally consult with the Division of Endangered Species and Habitat Conservation (DESHC), U.S. Fish and Wildlife Service.

#### D. ENVIRONMENTAL FATE and EXPOSURE ASSESSMENT

##### Hydrolysis

Supplemental data indicate that hydrolysis of diazinon is slow at a pH of 7 & 9 and faster at a pH of 5 in non-sterile water. Therefore hydrolysis is expected to slow in sterile water at a pH 7 and 9. Diazinon appears to be more stable at a pH of 7 with a half life of over a month. Although definitive half-life values cannot be determined from available data, the rate of hydrolysis could be attributed to microbial degradation in non-sterile water.

##### Photodegradation in Soil

<sup>14</sup>C Diazinon degrades in sandy loam soil with a half-life of 17.3 hours (14.7 days in the dark) when exposed to natural sunlight. The major degradate, oxypyrimidine, was detected at maximum concentrations of 23.72% (32.6 hours) after exposure to sunlight and 17.40% (216 hours) in the dark controls. The degradate 2-(1'-hydroxy-1'-methyl)ethyl-4-methyl-6-hydroxypyrimidine was formed only under natural sunlight at a level of 36% after 8 hours. An unidentified degradate accounted for about 7% of the applied material as a result of non-photolytic degradation since it was also present in the non-exposed samples. No additional data are required.

##### Soil Degradation

Diazinon degrades rapidly under aerobic, anaerobic, aquatic anaerobic and sterile soil conditions with the following half-lives:

Aerobic	31.2 days
Anaerobic	34.3 days
Aquatic anaerobic	4.0 days*
Sterile	46.0 days

\* The faster degradation of diazinon under this condition might be attributed to hydrolysis under the acid aqueous conditions of the study.

Microbial degradation appears to be the major pathway for the degradation of diazinon; however as demonstrated by the degradation half-lives under the various soil conditions, degradation continues in sterile and anaerobic soil conditions, which represent conditions of reduced microbial activity. The most probable mechanism responsible for degradation under sterile and anaerobic soil conditions appears to be chemical hydrolysis in acidic soils.

Under neutral and alkaline conditions, diazinon could be expected to persist longer in anaerobic systems where the main pathway of degradation is chemical as opposed to microbial.

Oxypyrimidine, the major soil degradate, is more persistent than diazinon under aerobic, anaerobic, and aquatic anaerobic soil condition reaching the following levels as percent of applied diazinon:

Aerobic	95 days accounting for 67% of the original $^{14}\text{C}$ dose.
Anaerobic	30 days accounting for 12.7% of the original $^{14}\text{C}$ dose.
Aquatic Anaerobic	15 days accounting for 54% of the original $^{14}\text{C}$ dose.

A second degradate was identified as 2-(1-hydroxyl-1-methyl)ethyl-4-methyl-6-hydroxypyrimidine, differing from oxypyrimidine only by an alcohol group. It reached a maximum concentration in 6 months accounting for 12.8% of the original  $^{14}\text{C}$  dose. Two additional unknown degradates were observed. They were not identified as they formed in amounts <1.0% of the original  $^{14}\text{C}$  dose in the aerobic and anaerobic soil study systems.

The data requirements for aerobic, anaerobic and aquatic anaerobic soil metabolism (laboratory) studies have been fulfilled. Additional data are required for aerobic aquatic soil metabolism.

#### Leaching and Adsorption/Desorption

In an acceptable unaged soil column leaching study, residues of diazinon were observed in four soil types; sand, sandy loam, silt loam, and clay. Approximately 81% of the applied unaged radio-active diazinon residues leached through a 30 cm Maryland sand column, 16% through a Maryland clay column, 6% through a Mississippi silt loam column, and 17.5% through a California

sandy loam column with the application of 50.8 cm of water. Oxypyrimidine, the major degradate, was the primary component in the leachates of all soil types. The parent diazinon was present in each soil type but only in small amounts.

In an aged soil column leaching study, residues of diazinon were observed in the leachate of a 30 cm sandy soil column at a pH of 7.8 when leached with 50.7 cm of water. About 32.7% of the applied material leached through the Collomeby sand soil column and 25.3% through the sandy loam soil column. Most of the leaching occurred with the initial application of less than 30 cm of irrigation. In addition to the primary degradate, oxypyrimidine, another major degradate, 2-ethyl-4-methyl-6-hydroxy pyrimidine was identified. This degradate was not identified in the aerobic soil metabolism study. Although this study does not satisfy Agency data requirements for an aged leaching study, it can be upgraded with submission of data that fully characterizes the second degradate.

#### HUMAN NONDIETARY EXPOSURE

Exposure estimates were made for turf and chinese cabbage, broccoli, and lettuce using available data and an adaptation of the method suggested in the Pesticide Assessment Guidelines subdivision K (Non-Detectable Residue Method). The exposure for a 10 kg child playing on turf treated with diazinon after the spray has dried on day of application was calculated to be 0.000031 mg/kg/hr. This estimation was based on an application rate of 10.89 lb/A, which is higher than the current label rate and without the subsequent application of water to dissolve or incorporate if granular. It is therefore a conservative estimate of exposure.

Foliar dislodgeable residue data representing a worst case for dissipation and exposure, citrus application with the most retentive type of formulation (wetttable powder) in an arid region of California were reviewed. Estimated fieldworker exposure values using the above criteria were 3.2 mg/hr on day 1; 0.57 mg/hr on day 2; and declined to 0.036 mg/hr by day 5. These exposure values would be applicable for diazinon applications of 2.0 lb ai/A or lower.

A reentry interval has been proposed but can not be accepted until all applicable data have been reviewed. In order to establish a reentry interval, an Allowable Exposure Level (AEL) must be estimated. Data submitted to establish a reentry interval were used to calculate an AEL of 0.875 mg/hr. If the AEL is accepted, the 24-hour reentry interval for all commercial agricultural crop uses including greenhouses and the statement allowing children to play on home lawns after spray has dried would be acceptable.

An interim reentry interval of 24-hours will be imposed for commercial agricultural uses involving hand labor (see PR Notices 83-2 and 84-1 for a description of hand labor agricultural practices) and commercial greenhouse uses.

### Poisoning Incidents

During 1961, 1969, 1973, and 1974, when accidental deaths due to pesticides in the U.S. were counted, diazinon was found to be the sixth most frequent cause of death. Diazinon averaged 2.5 deaths per year during the survey (Hayes, W.J. and Vaughn, W.K., 1977). California, which kept count of all accidental pesticide-related deaths, reported two diazinon related fatalities during the time period 1965 through 1977. One fatality was a child, the other was an adult poisoned in a non-occupational case (CDFA 1965-1977).

A sampling of 12% of hospitals nationwide was conducted from 1974 to 1976 to estimate pesticide-related hospitalizations. During this period, diazinon was estimated to have caused 88 hospitalizations based on the sample. The survey ranked diazinon as the sixth most frequent cause of pesticide poisonings. Twelve percent of the diazinon hospitalizations were from occupational exposure, 61% from non-occupational exposure and home use, 24% from intentional ingestion, and 3% from unknown causes (USEPA, 1985).

A 1984 survey of hospital emergency room pesticide-related cases indicated that diazinon accounted for 2% of the total. The survey concluded that of that total, 88% of the poisonings occurred in the home.

The Agency's Pesticide Incident Monitoring System (PIMS) report for diazinon was reviewed to determine the circumstances involved in diazinon poisonings. The poisonings were classified as: 1) Intentional Ingestion; 2) Accidental Ingestion; 3) Homeowner Misuse. The report concluded that poisonings from agricultural uses were uncommon and that poisonings generally were the result of improper use by the homeowner, for example, spraying into the wind or failure to remove contaminated clothing.

In a national survey of household pesticides use conducted in 1976 through 1977, diazinon was found to be the seventh most common pesticide used in the home, occurring in 3.2% of all households surveyed.

The State of California, the only state that enforces mandatory reporting of occupational pesticide incidents, reported 30 cases of illness or injury as a result of occupational exposure during 1987; (5) applicator ground, (6) applicator, hand-held equipment, (3) coincidental exposure, (1) emergency response personnel, (3) exposure to concentrate, non-use exposure, (3)



exposure to residues, agricultural field, and (9) exposure to residues, non-agricultural (CDFA 1987).

No poisoning incident data are available for 1981 through 1985.

#### Non-Dietary Exposure Assessment

A review of the poisoning incident data demonstrates that diazinon is a major source of pesticide-related poisonings in the home. The number of incidences appear to partially reflect the large quantities of diazinon used, particularly in the home. The relatively low levels of agricultural occupational poisonings suggest that current use practices do not lead to high numbers of acute poisonings. Improvement of the labelling language should help to lower the number of occupational poisonings that do occur.

The nature of the poisonings involving home uses demonstrate that homeowners are not properly equipped to safely handle many of the more concentrated formulations of diazinon, which have a higher toxicity,

#### D. TOLERANCE REASSESSMENT

Tolerances have been established for residues of diazinon in a variety of raw agricultural commodities, in meat, fat and meat byproducts (40 CFR 180.153), food additives (40 CFR 185.1750), food handling establishments (40 CFR 185.1750), and feed handling/processing establishments (40 CFR 186.1750). Tolerances for residues of diazinon are currently expressed as residues of diazinon per se. EPA has evaluated the residue and toxicology data supporting these tolerances. The following were considered during this evaluation:

- o Whether the current tolerances and food/feed additive regulations are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA sec. 24(c).

- o Whether group tolerances can be established in accordance with 40 CFR 180.34(f).

- o Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

- o Whether the tolerances are expressed accurately and in current terminology.

The regulatory determinations resulting from EPA's review are set out in Section IV.A., Regulatory Positions and Rationales.

## 1. Residue Data.

### a. Nature of the Residues in Plants and Animals:

The metabolism of diazinon in plants and animals is not adequately understood. Preliminary data suggests that diazinon in plants is oxidized to diazoxon (II)<sup>5</sup> which is in turn hydrolyzed to 2-isopropyl-4-methylpyrimidin-6-ol (III). The existence of hydroxydiazinon (IV) in kale samples treated with diazinon in the field could be caused by the effect of UV-irradiation. Preliminary data has tentatively identified several diazinon metabolites ( X and XI) in cow urine. Diazinon metabolites (VII), (VIII), and (IX) have been identified in rat urine.

### b. Analytical Methodology:

Adequate sulfide, phosphorus, pyrimidine, cholinesterase inhibition , GC, and GLC methods are available for collection of data pertaining to residues of diazinon in or on plant commodities, with exception of the cholinesterase method or the colorimetric methods which specify surface stripping rather than grinding or homogenation of plant samples. A colorimetric sulfide method is also adequate for the determination of diazinon in animal commodities. The sulfide method (Method II(a) in PAM, Volume II, Pesticide Regulation § 180.153) is subject to interference from thiocarbamates and crops with high thiol content ( such as cabbage, kale, turnips, radish, collards, Brussels sprouts, and mustard greens). Therefore, for regulatory purposes, the Agency recommends Method II(c) in PAM, Vol. II which has an additional column clean up step for crops with high thiol content. Both diazinon and its metabolite, diazoxon, are determined by the phosphorus method. The pyrimidine procedure detects diazinon and the potential metabolites (see table 1).

The cholinesterase inhibition procedure is subject to natural interference and will measure other thiophosphate insecticides if present. Successful method trials of the sulfide method have been completed on various commodities, but recoveries from beef fat were relatively poor at fortification levels of 0.25-0.05 ppm. The GC or GLC method can be used as a confirmatory or an alternative method to determine the residues of diazinon and its metabolites.

Diazinon is determined by multiresidue procedures published in the Pesticide Analytical Manual Vol. I. No additional data are required as per 40 CFR § 158.240(b)(15).

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<sup>5</sup> See table 1 for identification of diazinon metabolites.

c. Storage Stability:

No data are available to determine the stability of diazinon or its metabolites in plants under storage conditions.

All of the plant residue and animal feeding data requested in this standard must be accompanied by information pertaining to the conditions and duration of sample storage prior to residue analysis and on the stability of diazinon under the storage conditions used.

It should be noted that the nature of the residue in plants and in animals has not been adequately described. If the requested metabolism data indicate the presence of residues of toxicological concern in plant and in animals commodities, data depicting the stability of such residues in storage will be required.

d. Magnitude of the Residues in Raw Agricultural Commodities and food and feed items:

Available data are not adequate to support many of the established tolerances for diazinon, excluding coffee beans, guar beans and guar forage. Data on the magnitude and levels of residues of diazinon and its metabolites in individual raw agricultural commodities and food and feed items are required.

e. Magnitude of the Residue in Meat, Milk, Poultry, and Eggs:

The adequacy of the established tolerances for meat, milk, poultry and eggs cannot be determined at this time. The nature of the residues in ruminants (including milk) and in poultry (including eggs) is not adequately understood. Additional data are required for raw agricultural commodities and processed products comprising animal feeds.

f. Food Handling Establishments:

No numerical tolerances have been established covering residues of diazinon in foods resulting from treatment of food handling establishments. Data are required depicting residues of concern in or on food resulting from applications of diazinon in a food service, food manufacturing, or a food processing establishment.

Table 1. Diazinon and its metabolites in plants and animals.

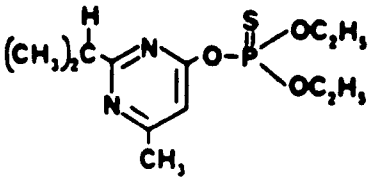
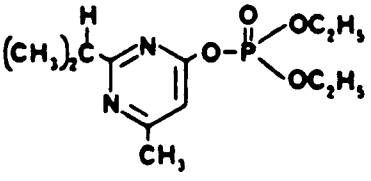
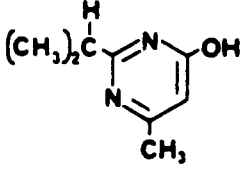
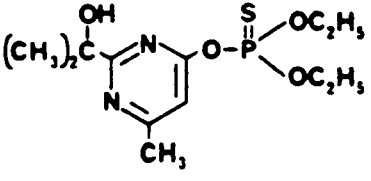
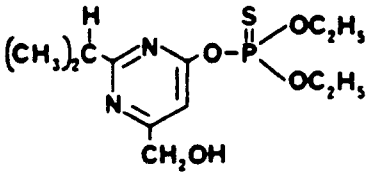
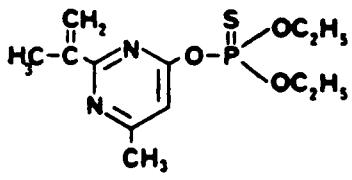
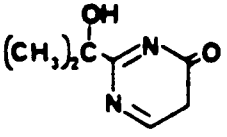
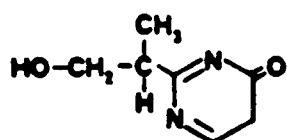
CODE	STRUCTURE	CHEMICAL NAME	COMMON NAME OR ABBREVIATION
Ia		0,0-diethyl 0-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate	Diazinon
IIa		0,0-diethyl 0-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphate	Diazoxon
IIIa		2-isopropyl-4-methylpyrimidin-6-ol	--
IVab		0,0-diethyl 0[2-(2'-hydroxy-2'-propyl)-4-methyl-6-pyrimidinyl] phosphorothioate	Hydroxydiazinon
Vb		0,0-diethyl 0-[2-(1-methylethyl)-6-hydroxymethyl-4-pyrimidinyl] phosphorodithioate	--
VId		0,0-diethyl 0-[2-(1-methylvinyl)-6-methyl-4-pyridinyl] phosphorothioate	--
VIIc		2-(1-hydroxy-1-methylethyl)-4-pyrimidinone	--

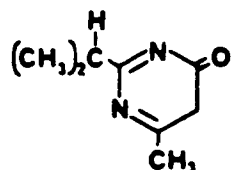
Table 1. (Continued).

VIII<sup>c</sup>



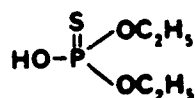
2-(1-methyl-2-hydroxyethyl)-  
4-pyrimidinone

IX<sup>c</sup>



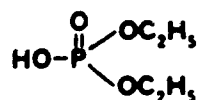
6-methyl-2-(1-methylethyl)-  
4-pyrimidinone

X<sup>d</sup>



Diethyl phosphorothioic  
acid

XI<sup>d</sup>



Diethyl phosphoric acid

<sup>a</sup>Identified in plants.  
<sup>b</sup>Identified in sheep tissues.  
<sup>c</sup>Identified in rat urine.  
<sup>d</sup>Identified in cow urine.

## 2. Tolerances issued.

Codex MRL's, Canadian, and Mexican tolerances have been established for diazinon in a number of commodities. Compatibility of these tolerances to that of U.S. tolerances cannot be determined until all additional metabolism and residue studies are available.

## 3. Toxicology Data.

Based on inhibition of plasma cholinesterase observed in a 90 day rat feeding study a NOEL of 0.009 mg/kg/day was established. A provisional acceptable daily intake (PADI) has been established at 0.00009 mg/kg/day utilizing an uncertainty factor of 100. The PADI is provisional because the existing data base on diazinon is lacking chronic feeding studies, and a multi-generation reproduction study.

The Theoretical Maximum Residue Contribution (TMRC) adjusted for percent of crop treated for the U.S. population average was calculated at 0.000767 mg/kg/day corresponding to 852% of the PADI. The TMRC is based upon current published tolerances and adjusted for percent of crop treated. It should be noted that the amount of pesticides used on crops that are grown on only a few acres and the amount of less commonly used pesticides on more important crops are difficult to determine; therefore it is likely that usage has been overestimated and the actual percent crop treated may be lower.

Moreover, the TMRC represents a worst case estimate of exposure that assumes that all crops are treated at the maximum rate and minimum pre harvest interval. The use of the TMRC also assumes that all commodities bear residues at the maximum level and that all persons consume these commodities. These assumptions lead to a conservative estimate of dietary exposure.

The Agency is not able to calculate an Anticipated Residue Contribution, which is a more realistic estimate of dietary exposure, since no processing or anticipated residue data are available. When the required data are submitted, the Agency will conduct a full tolerance reassessment.

### References Cited

1. CDFA, California Department of Food and Agricultural (1987) Summary Tables of Reports from Physicians of Possible Illnesses Related to Pesticide Exposure During January 1-December 31, 1987 in California. Unpublished report, Worker Health and Safety Branch, CDFA, HS-1493.
2. CDFA, California Department of Food and Agricultural (1985) Summary Tables of Reports from Physicians of Possible Illnesses Related to Pesticide Exposure During 1965-1977 and 1981-1985 in California. Unpublished reports, Worker Health and Safety Branch, CDFA, HS-322, HS-545, HS-1098, HS-1186, HS-1188, HS-1304, HS-1305, HS-1370, and HS-1371.
3. Hayes, W.J. and Vaughn, W.K. (1977). Mortality from pesticides in the United States in 1973 and 1974. Toxicology and Applied Pharmacology 42:235-252.
4. USEPA (1985) Evaluation of Epidemiologic Factors from Two National Studies of Hospitalized Pesticides Poisonings. USEPA report (October 1985).

#### IV. REGULATORY POSITION AND RATIONALE

##### A. REGULATORY POSITIONS AND RATIONALES

Based on review and evaluation of all available data and other relevant information on diazinon, the Agency has made the following determinations:

###### 1. Special review

The Agency is deferring a decision at this time on whether to place diazinon into Special Review for its potential hazard to non-target species resulting from its use on agricultural crops, on turf and other grassy sites (eg., athletic fields, recreational parks, home lawns).

Rationale: The Agency is assessing the magnitude of the potential hazard to non-target species from the application of diazinon formulations on agricultural crops and on grassy sites. The available laboratory, field toxicity studies, residue and exposure studies, and bird kill incidents are being closely examined to determine whether or not a Special Review or other types of regulatory actions are appropriate for this issue of concern to the Agency. Upon completion of the examination, a decision will be made.

###### 2. Restricted Use [Commercial Outdoor Uses]

The Agency is classifying all commercial outdoor uses (eg., agricultural crops, ornamentals, and turf) of diazinon for restricted use, based upon its known toxicity to birds and aquatic species.

Rationale: Diazinon meets the criteria of 40 CFR 152.170 due to its high avian and aquatic toxicity. Without further restrictions, the Agency concludes that current commercial agricultural uses of diazinon may pose an adverse risk to birds and aquatic invertebrates.

###### 3. Restricted Use [Residential End-Use]

All diazinon end-use products that are in Toxicity Category I or II (DANGER or WARNING) and bear product labeling that directly recommends residential use or reasonably can be interpreted to permit residential use are classified for restricted use. Such products may be used only by certified applicators or persons under their direct supervision. In the past, the Agency has allowed these types of products to be labeled , "For Agricultural Use Only" or "For PCO Use Only". However, these statements are not enforceable.



Rationale: Diazinon end use products in Toxicity Categories I and II intended for residential/institutional use meet the criteria for restricted use in 152.170; (i) incident information (see Section III, Poisoning Incidents) show that a large number of incidents involving diazinon (61% in one hospital survey) were reported to have occurred from residential use, (ii) available toxicity data places these end use products in toxicity categories I and II for acute oral toxicity, (iii) current or revised precautionary statements would not sufficiently minimize the risks to homeowners, and (iv) the use of protective clothing generally not expected to be available to the general public. Statements purporting to limit application to commercial applicators or PCOs are not enforceable. Classification for restricted use will ensure that these products are used only by persons who have been trained in proper application techniques to minimize hazardous exposures.

#### **4. Homeowner Precautionary Statements**

The Agency is imposing additional protective clothing and use instructions statement for all end-use products intended for use in and around the home. Refer to section IV.D. which specifies labeling language to be used.

Rationale: Due to the number of homeowner poisoning incidents, the Agency believes that additional labeling statements are warranted in order to provide additional use and safety information to the homeowner.

#### **5. Toxicity Testing with Typical End Use Products**

The Agency will be requiring the following testing of a series of typical end use products: acute oral, acute dermal, primary dermal irritation, primary eye irritation, dermal sensitization, and acute inhalation if appropriate. The Agency will reserve alternative product formulations testing, pending submission and review of toxicity testing on the stabilized technical diazinon products (manufacturing use products).

Rationale: These tests are necessary to ensure that end use product is properly labeled with respect to human and hazard signal word and precautionary statements. Available data do not adequately characterize the toxicity profile of diazinon end-use products. The Agency will conduct a toxicological assessment of the data submitted and determine whether additional regulatory action is necessary.

## 6. Bridging Toxicity Testing with Manufacturing Use Products

The Agency will require each registrant of a manufacturing use product to submit the following toxicity studies on their current formulations: acute oral, acute dermal, acute inhalation, primary dermal irritation, primary eye irritation, dermal sensitization, and a 6-week rat feeding study. The Agency may require additional toxicity testing based upon its evaluation of these studies.

Rationale: The Agency is concerned with reported contamination of technical diazinon with tetraethylpyrophosphate (TEPP) sulfotep, and monotepp, and other potentially highly potent organophosphate cholinesterase inhibitors which may be formed during the manufacturing process. Since manufacturing processes are not the same for all technical products and different manufacturing processes may result in different levels of contaminants, the Agency believes that different stabilized diazinon technical products may have substantially different acute and/or subacute toxicity characteristics. In order to evaluate the toxicological similarities and/or dissimilarities of the currently registered manufacturing use products the above listed studies must be conducted.

## 7. Endangered Species

The U.S. Fish and Wildlife Service, Division of Endangered Species and Habitat Conservation (DESCH) has determined that certain uses of diazinon, including uses on corn and sorghum may jeopardize the continued existence of endangered species. Based on this determination, DESCH specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species by these uses.

No additional labeling is being required at this time. As explained below, labeling requirements issued in PR Notices 87-4 and 87-5 have been withdrawn pending re-issuance.

Rationale: Diazinon is very highly toxic to avian species, both on a acute and dietary basis. The acute LD50 for birds is less than or equal to 10 mg/kg for terrestrial, aquatic and songbird species. The dietary LC50s for avian species are in the range of 47 - 245 ppm.

Diazinon is also highly toxic to fish: the fish LC50 for technical diazinon ranges from 90 ug/L for rainbow trout to 1700 ug/L for cutthroat trout. The LC50 in freshwater invertebrates is 1.4 ug/L or less.

Endangered species of avian and aquatic species may be at a greater risk from use of diazinon than the species tested.

In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to FWS findings that certain pesticides, including this chemical, jeopardized the continued existence of endangered species. Those PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of the pesticide within the range of jeopardized endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988 the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species.

EPA is working to correct these errors prior to requiring labeling to protect endangered species. When that program is fully developed, notice of any labeling necessary to protect endangered species will be issued.

#### **8. Reentry Interval**

The Agency will impose an interim 24-hour reentry interval for commercial greenhouse uses and commercial agricultural uses, identified under PR Notices 83-7 and 84-1, of diazinon.

Rationale: Data to establish a definitive reentry interval for diazinon have recently been submitted and are currently under review. The 24-hour interim reentry interval is based upon the AEL, 0.875 mg/hr, and the decline in worker exposure below the AEL by day 2, 0.57 mg/hr.

#### **9. Worker Safety and Protective Clothing**

The Agency is revising worker safety and protective equipment statements for end use products containing diazinon. Section IV.D. specifies the wording for products in Toxicity Categories I, II and III.

Rationale: Current protective clothing requirements for diazinon are not adequate to minimize exposure to agricultural workers. The Agency is concerned that exposure to diazinon could present a health risk to agricultural workers due to the high acute toxicity of certain end use formulations of this pesticide.

## 10. Groundwater Concerns

The Agency is not imposing a ground water contamination advisory statement for diazinon products at this time.

The Agency will assess the potential of diazinon for groundwater contamination after receipt and review of environmental fate data and will determine whether regulatory action is necessary.

Rationale: The Agency is unable to fully assess the potential for diazinon to contaminate groundwater. Preliminary data indicate that diazinon degrades rapidly under aerobic, anaerobic, aquatic anaerobic, and sterile soil conditions. However, diazinon's major soil degradate, oxypyrimidine, is more persistent than diazinon under similar soil conditions.

## 11. Non-Target Species Labeling

In order to meet the statutory standard for continued registration, the Agency has determined that diazinon products must bear revised and updated labeling for hazards to nontarget species.

Rationale: Labeling statements are required since available data show that diazinon is extremely toxic to birds, non-target insects, and aquatic organisms.

## 12. Tolerance Revocation

The Agency will propose tolerance revocation for rutabagas, red chicory tops, and dandelions (40 CFR 180.153).

Rationale: Currently there are no registered products bearing these uses.

## 13. Tolerance Proposals

Residue data must be submitted and tolerances must be proposed for corn fodder and forage, and either sorghum forage and fodder, or wheat forage, hay and straw, and soybean straw and hay.

Rationale: Currently there are no established tolerances to cover residues of diazinon on these commodities. Residue data are not available to determine appropriate tolerance levels for expected residues in or on these commodities.

#### 14. Grazing and Feeding Restrictions

For the following crops; sorghum fodder and forage, soybean straw and hay, and sugarcane forage, the registrant is given the choice of developing and submitting data in support of tolerances, or of adding label restrictions against the feeding and grazing of treated crops to livestock. Each registrant must inform the Agency by 90 days of receipt of this Registration Standard which option he chooses. If he selects the label restrictions, labeling submitted at the 9 month deadline must include the grazing/feeding restrictions.

Rationale: These raw agricultural commodities are used as feed and forage for livestock and tolerances are required.

#### 15. Tolerances and New Uses<sup>6</sup>

The Agency will not grant any significant tolerances or any significant food uses for diazinon until the required residue chemistry and toxicology studies have been submitted and reviewed.

Rationale: The Agency needs additional residue, plant, and animal metabolism data in order to characterize the nature of residues in plants and animals. In addition storage stability data are required before a tolerance reassessment for diazinon can be performed.

#### 16. Established Tolerances

The Agency is not requiring additional residue data to support the established tolerances for diazinon in or on guar beans and coffee beans.

Rationale: Sufficient residue data are available to determine the adequacy of the established tolerances for diazinon in or on these commodities (40 CFR 180.153).

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<sup>6</sup> New Uses is defined in 40 CFR 152.3 (p). In the case of a new food or use, the Agency will generally consider as significant an increase in the Theoretical Maximum Residue Contribution (TMRC) of greater than 1%.

## 17. Commodity Definitions

The Agency will revise commodity definitions for certain raw agricultural commodities listed in 40 CFR 180.153.

- a) Tolerance listing "peas with pods (determined on peas after removing any shell present when marketed)" will be revised to read, "peas, succulent".
- b) Tolerance listing "bean forage" will be revised to read, "bean vines".
- c) the tolerance listing for "wheat forage and straw" was omitted from listing and will read "wheat forage and straw 0.05 ppm".

Rationale: These listings in 40 CFR 180.153 are not accurate, or do not use current terminology.

## 18. Uses not Supported

The Agency is aware that the following crop uses will not be supported by the principal end use product registrant. If these uses are not supported by other technical producers, end use registrants will be required to provide appropriate data, delete the uses from their labels, or face suspension of their products.

### Fruits and Nuts:

grapefruit	lemons	limes,
oranges	tangelos	tangerines,
kumquats	citrus citron	hybrids of citrus fruits,
blueberries	coffee	figs,
olives	filberts	pecans.

### Vegetables, Foliar and/ or Preplant

beans (dried varieties),	peas (dried varieties),
beans, pinto	mushrooms,
watercress.	

### Field & Forage Crops

alfalfa	clover	trefoil,
cotton	cowpeas	lespedeza,
peanuts	sorghum	soybeans,
sugarcane	tobacco,	
corn, field		

### Range, Pasture, & Grassland

Burmudagrass	rangeland	pasture,
grass forage.		

Rationale: The Agency believes it is prudent to provide end use formulators with current information that may have a significant effect on their registrations and to provide an efficient means to disseminate this information to the end use formulator.

#### 19. Establishment of Common Name

The common name "diazinon" will appear before the chemical name on the pesticide label. Labels must be revised to reflect this. Refer to section IV.D.

Rationale: The common name "diazinon" has been accepted by the American National Standards Institute, Inc. (ANSI). The Agency uses common names to encourage familiarity with pesticide names.

#### 20. Inert Ingredients

Petroleum distillates and xylene based solvents appearing on the product label as actives must be declared as inert ingredients or the registrant must provide information substantiating its active classification. In addition, all products containing more than 10% of either solvent must identify the petroleum distillate or xylene by name as a substatement to the ingredient statement.

Rationale: Petroleum distillates and xylene based solvents contained in diazinon end use formulations have not been identified as causing a pesticidal effect and are not considered as active ingredients.

#### 21. Studies that will receive Immediate Review.

The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain of the data being required by the Agency are essential to resolve risk concerns, or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to receive priority review as soon as they are received by the Agency:

- 158.240 Residue Chemistry
  - Plant and Animal Metabolism
  - Special Storage Stability (EUP)
- 158.290 Environmental Fate
  - Hydrolysis
  - Photolysis

158.340 Toxicology

- Acute Toxicity Studies (MUP)
- 6-week oral feeding study (MUP)
- Acute delayed neurotoxicity
- Acute Toxicity Studies (TEP)

158.490 Ecological Effects

**22. Continuation of registration**

While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing diazinon may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7)).

Issuance of this Standard provides a mechanism for identifying data needs and labeling changes arising from available data. Required data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary.



## B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain diazinon, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

## C. ACCEPTABLE RANGES AND LIMITS

### 1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain this pesticide. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent, except for those impurities of toxicological importance (TEPP and its sulfur derivatives and oxo-diazinon) for which upper certified limits of less than 0.1% may be indicated.

### 2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing this pesticide provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

### 3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed in the EPA Compendium of Acceptable Uses (for availability, see page 1). The Compendium lists all registered uses, as well as approved maximum application rates and frequencies.

## D. LABELING

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing this pesticide may be released for shipment by the registrant after March 31, 1990, unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing this pesticide may be distributed or sold after March 31, 1991, unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

#### 1. Ingredients Statement

The ingredient statement for products must list the active ingredient as:

##### ACTIVE INGREDIENT

Diazinon [O,O-Diethyl O-(2-isopropyl-6-methyl-4-pyrimidinyl) phosphorothioate] . . . . . %

All products containing petroleum distillates, xylene, or xylene range solvent must identify these in a substatement to the ingredients statement. The following statement is acceptable for this purpose: "Contains [petroleum distillate, xylene, xylene range solvent]," as appropriate.

#### 2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in the EPA Compendium of Acceptable Uses (for availability see page 1). However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

#### 3. Precautionary Statements

##### STATEMENTS FOR MANUFACTURING-USE PRODUCTS

##### Environmental Hazards Statement:

"This pesticide is highly toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the Environmental Protection Agency."

## STATEMENTS FOR END-USE PRODUCTS

### 1. Restricted use Statement

- a. The following statement must appear on the front panel of all products for commercial outdoor use.

RESTRICTED USE PESTICIDE  
Due to Avian and Aquatic Toxicity

For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification

- b. The following statement must appear on the front panel of all products intended for residential use by homeowners in Toxicity Category I or II (Danger or Warning).

RESTRICTED USE PESTICIDE  
Due to Acute Toxicity

For retail sale to and use only by Certified Applicator or persons under their direct supervision and only for those uses covered by the Certified Applicators's Certification

### 2. Dermal Sensitization Statement:

The following statement must appear in the Precautionary Statement Section.

"May cause contact sensitization following repeated contact following repeated contact with skin in susceptible individuals. Avoid repeated contact with skin. If sensitization reactions results consult a physician".

### 3. Environmental Hazards Statement:

The following statement must appear on **non-granular** formulations.

"This pesticide is highly toxic to birds, fish, and wildlife including waterfowl. Birds and waterfowl feeding or drinking on treated areas may be killed. Because of the migratory habits of certain Atlantic Coast waterfowl, do not apply this

product in Nassau County, New York between November 1 and May 20. Do not exceed maximum permitted label rates above those recommended significantly increase potential hazards to birds and waterfowl. Avoid overlapping of sprays. Where irrigation (watering) is recommended apply a minimum of 0.25 inch of water immediately after application. Stop irrigation before puddling occurs. Keep out of lakes, streams, ponds, tidal marshes and estuaries (except for effluence from treated watercress beds). Do not apply to water that will be used for recreational purpose and human and livestock consumption. Shrimp and crab may be killed at applications rates recommended on this label. Do not apply where fish, shrimp, crab, and other aquatic life are important resources.

The following statement must appear on all **granular formulations applied by ground equipment**.

"This pesticide is highly toxic to fish and wildlife. Birds feeding in treated areas may be killed. Do not apply directly to water or wetlands (swamps, bogs, marshes, and pot-holes). Runoff maybe hazardous to aquatic organisms in neighboring areas. Collect or incorporate granules that are spilled during loading or are visible on soil surface in turn areas. Do not contaminate water when disposing of equipment washwaters".

The following statement must appear on all **granular formulations applied by aerial applications**.

"This pesticide is highly toxic to fish and wildlife. Birds feeding in treated areas may be killed. Do not apply directly to water or wetlands (swamps, bogs, marshes, and pot-holes). Drift and runoff maybe hazardous to aquatic organisms in neighboring areas. Collect granules that are spilled during loading ".

#### 4. Bee Caution Statements:

The following statement must appear on all products intended for outdoor use (excluding granular formulations).

" This pesticide is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this pesticide or allow it to drift to blooming crops or weeds if bees are visiting the treatment area."

An additional auxiliary environmental statement should be placed in the use directions as appropriate.

Foliar application to alfalfa, peas, or beans: "Do not apply if the crop or weeds in the treatment area are in bloom."

Foliar application to corn: "Do not apply to corn during the pollen shed period."

Foliar application to fruit trees (apple, cherry, peach, plum, and citrus): "Do not apply when trees or substantial numbers of weeds in the orchard (grove) are in bloom."

5. Homeowner Protection Statements:

The following statements must appear on all liquid products intended for, or packaged for use in or around the home, excluding pet collars, insect tapes, and dust formulations.

**"Indoor Domestic Use:** Do not spray in the immediate area when others are present. After application open windows and/or doors to provide adequate fresh air ventilation to the room(s). Remove clothing after spraying and launder before reuse."

**"Outdoor Domestic Use:** Wear a long sleeve shirt and long legged pants. Spray with the wind to your back. Do not spray on windy days (wind speed is greater than 10 miles per hour). Remove clothing after spraying and launder before reuse. If clothing becomes wet from spray, **stop spraying**, immediately remove clothes and shower with soap and water."

"Do not allow children or pets onto a treated area until the spray has dried." or "Do not allow children or pets on treated area until granules have been watered into soil and grass has dried."

6. Non-Domestic Protection Statements:

For those products registered for use in hospitals and/or nursing homes the following statement must appear in the precautionary statement section.

" Do not apply this pesticide in patient rooms or in any room occupied by the infirm, elderly, or children for extended periods of time."

For those products registered for use in schools the following statement must appear in the precautionary statement section.

" Do not apply this pesticide when class rooms are in use."

For those products registered for commercial use in institutions (including but limited to office buildings, museums, libraries, sports facilities, etc.) the following statement must appear in the precautionary statement section.

" Do not apply this pesticide in the immediate area when occupants are present."

## 7. Food and Feed Handling Establishments

a. For those products registered for Crack and Crevice and Spot Treatments in the food/feed areas of restaurants or other areas where food/feed is commercial prepared or processed, the following statements must appear in the Direction for Use section.

**Feed and Food Handling Establishments Crack and Crevice and Spot Treatments**- Places other than private residences, in which food is held, processed, prepared and/or served.

**FOOD AND FEED ESTABLISHMENTS**- Apply [your product name] as either a spot or crack and crevice treatment as directed below.

**Food/Feed Areas**- Includes receiving, serving, storage (Dry, Cold Frozen, Raw), packaging (cleaning, slicing, cooking, grinding), edible waste storage, enclosed processing systems (mills, dairies, edible oils, syrups).

**SPOT TREATMENT-FOOD/FEED AREAS**- Limit spot treatments to floor surfaces when pests have been seen or where they are suspected of hiding. Limit individual spot treatments in food/feed areas to an area no larger than 20 percent of the floor. Any individual spot treatment shall not exceed 2 sq. feet. Do not apply to areas, surfaces, or utensils which will come in contact with food. Take extreme care to avoid contamination of food or food contact surfaces or introducing the material into the air.

**CRACK AND CREVICE TREATMENT**- Apply [your product name] spray in small amounts directly into cracks and crevices using equipment capable of delivering a pin stream of insecticide. Includes expansion joints, spaces between equipment and floors, and openings leading to voids and hollow spaces in walls, equipment legs and bases. Do not use this product in conduits, motor housings, and electrical switch boxes.

**APPLICATION OF THIS PRODUCT IN THE FOOD/FEED AREAS OF FOOD/FEED HANDLING ESTABLISHMENTS, OTHER THAN AS A CRACK AND CREVICE [AND SPOT] TREATMENT ARE NOT PERMITTED.**

**NON-FOOD AREAS**- Includes garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, mop closets and storage (after canning or bottling).

**NON-FOOD AREAS- SPOT TREATMENT**- As a spot treatment apply [your product name] as a coarse low pressure fan spray to floor surface areas around water pipes, beneath cabinets, refrigerators, sinks, stoves, storage areas, and similar areas where cockroaches, ants, spiders, and silverfish hide.

b. **NON FOOD/FEED AREAS OF FOOD/FEED HANDLING ESTABLISHMENTS**

For those products registered in the non-food/feed areas of food/feed handling establishments, restaurants or other areas where food/feed is commercially prepared or processed, the following statements must appear in the Direction for Use section.

Do not use in food areas of food handling establishments, restaurants or other areas where food/feed is commercially prepared or processed. Do not use in serving areas while food is exposed or facility is in operation. Serving areas where prepared foods are served such as dining rooms but excluding areas where foods may be prepared or held. In the home, all food processing surfaces and utensils should be covered during treatment or thoroughly washed before use. Exposed food should be covered or removed.

**NON-FOOD AREAS-** Includes garbage rooms, lavatories, floor drains (to sewers), entries and vestibules, offices, locker rooms, machine rooms, boiler rooms, mop closets and storage (after canning or bottling).

**NON-FOOD AREAS- SPOT TREATMENT-** As a spot treatment apply [your product name] as a coarse low pressure fan spray to floor surface areas around water pipes, beneath cabinets, refrigerators, sinks, stoves, storage areas, and similar areas where cockroaches, ants, spiders, and silverfish hide.

c. **USE IN MEAT AND POULTRY PLANTS**

Use in food-handling establishments can imply use in U.S. Department of Agricultural (USDA) Meat and Poultry Plants. Therefore, either add the statement, **"Not for Use in USDA MEAT AND POULTRY PLANTS"** or submit an application to USDA requesting use in these areas. If granted, you can then indicate on the label, **"For Use in USDA MEAT AND POULTRY PLANTS"**.



## 8. Worker Protection Statements

### Updated Worker Protection Statements for TOXICITY I and II END-USE FORMULATIONS OF DIAZINON.

#### WORK SAFETY RULES

REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SUSCEPTIBILITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.

If handled indoors provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is a danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way STOP work and get help right away, See Practical Treatment Section.

#### PERSONAL PROTECTIVE EQUIPMENT

WEAR THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT WHEN HANDLING THE CONCENTRATE: A protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet; chemical resistant gloves, chemical resistant apron, chemical resistant shoes, shoe coverings, or boots, and socks.

[Liquid Formulations Only]. If handling the concentrate with a closed system, a long-sleeved shirt and long-legged pants may be substituted for the protective suit; shoes and socks.

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT CLEANING AND REPAIR, DISPOSAL OF SPRAY SOLUTION, AND DURING REENTRY TO TREATED AREAS PRIOR TO THE SPRAYS HAVING DRIED (OR DUSTS HAVING SETTLED): A protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet; chemical resistant gloves, chemical resistant shoes, shoe coverings, or boots, and socks.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB OR COCKPIT, THE FOLLOWING PROTECTIVE CLOTHING MAY BE WORN AS AN ALTERNATIVE: A long-sleeved shirt, long-legged pants, shoes and socks. Chemical resistant gloves must be available in the cab or cockpit and must be worn when exiting. This clothing is inadequate to protect you during equipment repair, cleaning, reentry, or pesticide disposal work.

IMPORTANT! Before removing gloves, wash them with soap and water. Always wash hands, face, and arms before smoking, eating, drinking, or using the toilet.

AFTER WORK ACTIVITIES: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately from house hold articles. Store protective clothing separately from personal clothing after each use. Clothing and personal equipment heavily contaminated or drenched with diazinon must be destroyed according to state and local regulations.

HEAVILY CONTAMINATED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED. DURING AERIAL APPLICATION, HUMAN FLAGGERS MUST BE IN TOTALLY ENCLOSED VEHICLES.

#### Updated Worker Protection Statements for TOXICITY III END-USE FORMULATIONS of Diazinon.

#### WORK SAFETY RULES

REPEATED EXPOSURES TO CHOLINESTERASE INHIBITORS SUCH AS ARE CONTAINED IN THIS PRODUCT MAY, WITHOUT WARNING, CAUSE PROLONGED SUSCEPTIBILITY TO VERY SMALL DOSES OF ANY CHOLINESTERASE INHIBITOR.

If handled indoors provide mechanical exhaust ventilation.

Keep all unprotected persons, children, livestock, and pets away from treated areas or where there is a danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way STOP work and get help right away, See Practical Treatment Section.

#### PERSONAL PROTECTIVE EQUIPMENT

Wear the following protective clothing when handling the concentrate. Long-sleeved shirt and long-legged pants, shoes and socks.

WEAR THE FOLLOWING PROTECTIVE CLOTHING DURING APPLICATION, EQUIPMENT REPAIR AND CLEANING, DISPOSAL OF THE SPRAY SOLUTIONS: Long-sleeved shirt and long-legged pants, shoes and socks.

**FOR EARLY REENTRY (BEFORE THE 24-HOUR REENTRY INTERVAL HAS EXPIRED)** A protective suit of one or two pieces that covers all parts of the body except the head, hands, and feet; chemical resistant gloves, chemical resistant shoes, shoe coverings or boots.

**IMPORTANT!** Before removing gloves, wash them with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or using the toilet.

AFTER USING THIS PRODUCT: Wash hands, face, and arms with soap and water. Remove clothing that has become damp, wet, (or dusty) while using this product and wash them separately from household clothing. Clothing or gloves that have been heavily contaminated or drenched with diazinon must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

DURING AERIAL APPLICATION, HUMAN FLAGGERS MUST BE IN TOTALLY ENCLOSED VEHICLES.

9. Reentry Statements:

REENTRY

24-Hours for greenhouse and agricultural crops involving hand labor (PR Notices 83-7 and 84-1).

For Commercial/Industrial products registered for use on potatoes the following statement must appear in the Use Direction for that crop.

"Note: Do not apply to commercially grown potatoes which will be hand-harvested."

"Do not enter or allow entry into the treated area until the 24 hour reentry interval has expired, unless the person entering the area is wearing the personal protective equipment listed on the label".

"Do not apply this product in a way that will contact unprotected workers, either directly or through drift. Only protected handlers may be in the area during application".

## V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B<sup>7</sup>
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The data requirements listed in Table A.
2. The labeling requirements specified for manufacturing use products in Section IV.

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<sup>7</sup>Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products. The Agency has decided that, in most cases, it will not require the submittal of product-specific data for end-use products at this time. Therefore, most Registration Standards do not contain a Table C.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.
2. If eligible for the generic data exemption<sup>8</sup>, the data requirements listed in Table C.
3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.
4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.
2. If eligible for the generic data exemption, the data requirements listed in Table C.
3. The labeling requirements specified for end use products in Section IV.

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<sup>8</sup>If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

## VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.<sup>9</sup>

### A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

### B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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<sup>9</sup>Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.
2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person

who will be submitting the data that you may rely upon its submittal. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

- a. A list of the members of the consortium;
- b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
- c. Identity of the Registration Standard containing the data requirement;
- d. A list of the products affected (from all members of the consortium); and
- e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

a. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

b. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:



[Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

#### H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

#### I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

#### J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following

information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

#### VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6. (cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

#### VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registration Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

#### IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Office of Pesticide Programs  
OPP Mailroom (TS-767C)  
Environmental Protection Agency  
401 M St., SW  
Washington, D.C. 20460

Attn: Diazinon Registration Standard

##### A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

- a. Application for Pesticide Registration (EPA Form 8570-1).
- b. Two copies of any required product-specific data (See Table B).
- c. Three copies of draft labeling, including the container label and any associated supplemental labeling.
- d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

2. Within 9 months of receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

- a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).
- b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

- a. Two copies of any product-specific data, if required by Table C.
- b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.
- c. Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

- a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).
- b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

Three copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.



## I. DATA APPENDICES

## TEGUIDE-1

### GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient  
PAI = Pure active ingredient  
PAIRA = Pure Active ingredient, radio labeled  
TEP = Typical end use formulation  
MP = Manufacturing use product  
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food  
B = Terrestrial, non-food  
C = Aquatic, food  
D = Aquatic, non-food  
E = Greenhouse, food

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F = Greenhouse, non-food  
G = Forestry  
H = Domestic outdoor  
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

### TG GUIDE-3

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A  
Generic Data Requirements for Diazinon

<u>Data Requirement</u>	<u>Composition</u>	<u>Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)</u>	<u>Bibliographic Citation</u>	<u>Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?</u>	<u>Timeframe For Data<sup>a</sup>/ Submission</u>
<u>Part 158, Subpart C, Product Chemistry</u>					
<u>Product Identity and Composition</u>					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No <sup>1</sup> /		Yes <sup>2</sup> /	9 Months
61-3 - Discussion of Formation of Impurities	TGAI	No <sup>1</sup> /		Yes <sup>3</sup> /	9 Months
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis of Product Samples	TGAI	No <sup>1</sup> /		Yes <sup>4</sup> /	12 Months
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	TGAI	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
63-3 - Physical State	TGAI	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
63-4 - Odor	TGAI	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
63-5 - Melting Point	TGAI	No <sup>1</sup> /		Yes <sup>5,6</sup> /	9 Months
63-6 - Boiling Point	TGAI	No <sup>1</sup> /		Yes <sup>5,7</sup> /	9 Months

Table A  
Generic Data Requirements for Diazinon (cont'd)

<u>Data Requirement</u>	<u>Composition</u>	<u>Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)</u>	<u>Bibliographic Citation</u>	<u>Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?</u>	<u>Timeframe For Data Submission</u>
<u>Part 158, Subpart C, Product Chemistry</u>					
<u>Physical and Chemical Characteristics (cont'd)</u>					
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No <sup>1/</sup>		Yes <sup>5/</sup>	9 Months
63-8 - Solubility	TGAI or PAI	No <sup>1/</sup>		Yes <sup>5/</sup>	9 Months
63-9 - Vapor Pressure	TGAI or PAI	No <sup>1/</sup>		Yes <sup>5/</sup>	9 Months
63-10 - Dissociation Constant	TGAI or PAI	No <sup>1/</sup>		Yes <sup>5/</sup>	9 Months
63-11 - Octanol/Water Partitioning Coefficient	PAI	No <sup>1/</sup>		Yes <sup>5,8/</sup>	9 Months
63-12 - pH	TGAI	No <sup>1/</sup>		Yes <sup>5,9/</sup>	9 Months
63-13 - Stability	TGAI	No <sup>1/</sup>		Yes <sup>5/</sup>	9 Months
<u>Other Requirements</u>					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes

a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.

1/ Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

2/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

3/ A detailed discussion of all impurities that are or may be present at  $\geq 0.1\%$ , based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

4/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

5/ Physicochemical characteristics (color, physical state, odor, melting point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.

6/ Data required if the technical chemical is a solid at room temperature.

7/ Data required if the technical product is a liquid at room temperature.

Table A  
Generic Data Requirements for Diazinon (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes (cont'd)

8/ Data required if the technical product is organic or nonpolar.

9/ Data required if the technical substance is dispersible in water.



Table A  
Generic Data Requirements for Diazinon

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a</sup> / Submission
<u>\$158.240 Residue Chemistry</u>					
171-2 - Chemical Identity <sup>1/</sup>					
171-3 - Directions for Use	(See Index)				
171-4 - Nature of the Residue (Metabolism) - Plant	PAIRA	No		Yes <sup>2/</sup>	18 Months
171-4 - Nature of the Residue (Metabolism) - Livestock	PAIRA & Plant Metabolites	No		Yes <sup>3,115/</sup>	18 Months
71 171-4 - Residue Analytical Methods					
- Plant Residues	TGAI &	Partially	00034132,00057235,	Yes <sup>4/</sup>	18 Months
- Animal Residues	Metabolites		00061988,00089632, 00089634,00090324, 00090343,00125096, 00125557,00125620, 00127229,00129308, 00131006,00135470, 00135471,00140118		
171-4 - Storage Stability Data	TEP and Metabolites	No		Yes <sup>5/</sup>	18 Months (90 Days for Protocol)

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.240 Residue Chemistry</u>					
171-4 - Magnitude of the Residue in Plants					
- Root and Tuber Vegetables Group					
o Beets (Garden)	TEP	Partially	00125078	Yes <sup>6</sup> /	18 Months
o Carrots	TEP	Partially	00108982	Yes <sup>7</sup> /	18 Months
o Parsnips	TEP	Partially	00108982	Yes <sup>8</sup> /	18 Months
o Potatoes (Processed)	TEP TEP	Partially No	00106977	Yes <sup>9</sup> / Yes <sup>10</sup> /	18 Months 24 Months
o Radishes	TEP	Partially	00033669,00108982	Yes <sup>11</sup> /	18 Months
o Rutabagas	TEP	No		Yes <sup>12</sup> /	18 Months
o Sugar Beet Roots (Processed)	TEP TEP	Partially No	00055415	Yes <sup>13</sup> / Yes <sup>14</sup> /	18 Months 24 Months
o Sweet Potatoes	TEP	Partially	00106977	Yes <sup>15</sup> /	18 Months
o Turnip Roots	TEP	Partially	00033245,00033670, 00108982	Yes <sup>16</sup> /	18 Months

Table A  
Generic Data Requirements for Diazinon (cont'd)

<u>Data Requirement</u>	<u>Composition</u>	<u>Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)</u>	<u>Bibliographic Citation</u>	<u>Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?</u>	<u>Timeframe For Data Submission</u>
<u>§158.240 Residue Chemistry</u>					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Leaves of Root and Tuber Vegetables Group					
o Beet Greens	TEP	No		Yes <sup>17</sup> /	18 Months
o Chicory	TEP	No		Yes <sup>18</sup> /	18 Months
o Sugar Beet Tops	TEP	Partially	00055429	Yes <sup>19</sup> /	18 Months
o Turnip Tops	TEP	Partially	00033245,00108982	Yes <sup>20</sup> /	18 Months
- Bulb Vegetables Group					
o Onions (Dry Bulb)	TEP	Partially	00089485	Yes <sup>21</sup> /	18 Months
- Leafy Vegetables Group					
o Celery	TEP	Partially	00057235,00108980	Yes <sup>22</sup> /	18 Months
o Endive (Escarole)	TEP	Partially	00108982	Yes <sup>23</sup> /	18 Months
o Lettuce	TEP	Partially	00118036	Yes <sup>24</sup> /	18 Months
o Parsley	TEP	Partially	00108982	Yes <sup>25</sup> /	18 Months

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.240 Residue Chemistry</u>					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Cucurbit Vegetable Group (cont'd)					
o Winter Squash	TEP	Partially	00108982	Yes <sup>50</sup> /	18 Months
- Citrus Fruits Group					
o Grapefruit	TEP	Partially	00057665	Yes <sup>51</sup> /	18 Months
o Lemons	TEP	Partially	00125096	Yes <sup>51</sup> /	18 Months
o Limes	TEP	Partially	00057665	Yes <sup>51</sup> /	18 Months
o Oranges	TEP	Partially	00032884,00125096	Yes <sup>51</sup> /	18 Months
o Processed Commodities	TEP	No		Yes <sup>52</sup> /	24 Months
- Pome Fruit Group					
o Apples (Processed)	TEP	No		Yes <sup>53</sup> /	18 Months
	TEP	No		Yes <sup>54</sup> /	24 Months
o Pears	TEP	No		Yes <sup>55</sup> /	18 Months

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.240 Residue Chemistry</u>					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Stone Fruit Group					
o Apricots	TEP	Partially	00108980	Yes <sup>56</sup> /	18 Months
o Cherries	TEP	Partially	00057235,00061987	Yes <sup>57</sup> /	18 Months
o Nectarines	TEP	Partially	00108980	Yes <sup>58</sup> /	18 Months
o Peaches	TEP	Partially	00108980	Yes <sup>59</sup> /	18 Months
o Plums (Fresh Prunes)	TEP	No		Yes <sup>60</sup> /	18 Months
o (Processed)	TEP	No		Yes <sup>61</sup> /	24 Months
- Small Fruits and Berries Group					
o Blackberries	TEP	Partially	00055419	Yes <sup>62</sup> /	18 Months
o Blueberries	TEP	Partially	00055418	Yes <sup>63</sup> /	18 Months
o Boysenberries	TEP	Partially	00055420	Yes <sup>64</sup> /	18 Months
o Cranberries	TEP	Partially	00108982	Yes <sup>65</sup> /	18 Months
o Dewberries	TEP	No		Yes <sup>66</sup> /	18 Months

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.240 Residue Chemistry</u>					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Miscellaneous Commodities (cont'd)					
o Cottonseed (Processed)	TEP	Partially	00032881	Yes <sup>93</sup> /	18 Months
	TEP	No		Yes <sup>94</sup> /	24 Months
o Figs (Processed)	TEP	Partially	00089485	Yes <sup>95</sup> /	18 Months
	TEP	No		Yes <sup>96</sup> /	24 Months
o Hops (Processed)	TEP	Partially	00089485	Yes <sup>97</sup> /	18 Months
	TEP	No		Yes <sup>98</sup> /	24 Months
o Kiwifruit	TEP	No		Yes <sup>99</sup> /	18 Months
o Mushrooms	TEP	Partially	00066159,00140118	Yes <sup>100</sup> /	18 Months
o Olives (Processed)	TEP	Partially	00089442	Yes <sup>101</sup> /	18 Months
	TEP	No		Yes <sup>102</sup> /	24 Months
o Peanuts (Processed)	TEP	Partially	00033671	Yes <sup>103</sup> /	18 Months
	TEP	No		Yes <sup>104</sup> /	24 Months
o Pineapple	TEP	Partially	00055414,00055425,	Yes <sup>105</sup> /	18 Months
o Pineapple (Processed)	TEP	No		Yes <sup>106</sup> /	24 Months

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.240 Residue Chemistry</u>					
171-4 - Magnitude of the Residue in Plants (cont'd)					
- Miscellaneous Commodities (cont'd)					
o Sugarcane (Processed)	TEP	Partially	00106977	Yes <sup>107/</sup>	18 Months
	TEP	No		Yes <sup>108/</sup>	24 Months
o Tobacco	TEP	No		Yes <sup>109/</sup>	18 Months
o Watercress	TEP	Partially	00057665	Yes <sup>110/</sup>	18 Months
171-4 - Magnitude of the Residue in Meat/Milk/Poultry/Eggs					
- Fat, Meat, and Meat By- products of Beef and Dairy Cattle and Sheep	TGAI & Plant Metabolites	Partially	00089634,00090250, 00090343,00125557	Reserved <sup>111,115/</sup>	
- Milk	TGAI & Plant Metabolites	Partially	00089634,00090254 05005830	Reserved <sup>111,115/</sup>	
- Poultry and Eggs	TGAI & Plant Metabolites	Partially	00091533	Reserved <sup>111,115/</sup>	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.240 Residue Chemistry</u>					
171-4 - Magnitude of the Residue in Fish and Shellfish					
- Fish	TGAI & Plant Metabolites	No		Reserved <sup>112/</sup>	
171-4 - Magnitude of the Residue in Drinking and Irrigation Water	TEP	No		Yes <sup>113/</sup>	18 Months
171-4 - Magnitude of the Residue Resulting from Treatment of Food Handling Establishments	PAIRA & TEP	Partially	00084599,00109994	Yes <sup>114/</sup>	18 Months



Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes

Note: As used in these footnotes, the term "residues of concern" or "residues of toxicological concern" means the "total toxicological residue" as defined in EPA Guidelines Section O, Residue Chemistry, and using the toxicological testing methods as detailed in Section F, Hazard Evaluation: Humans and Domestic Animals. Residues of parent diazinon, any toxicologically significant organophosphorus impurities, degradates, and metabolites, as well as tetraethylpyrophosphate (TEPP) or sulfur derivatives of TEPP are of concern to the Agency and are covered by this definition. All requirements for determination of residues "in or on" require determination both in and on the specific crop/commodity/site.

- a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.
- 1/ The same chemical identity data are required as under §158.170, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.
- 2/ Data depicting the uptake, distribution, and metabolism of ring-labeled [<sup>14</sup>C] diazinon in representative mature crops, including a tree fruit such as peaches, and cotton, following soil and foliar application at a rate sufficiently high to permit complete <sup>14</sup>C-residue identification are required.

Representative samples from these tests must also be analyzed using accepted enforcement methods to ascertain that these methods will determine all metabolites of concern.

- 3/Animal metabolism studies utilizing ruminants and poultry are required. Ruminant studies must include a study involving oral administration of [<sup>14</sup>C] ring-labeled diazinon to cattle and a study involving the registered direct animal treatment for sheep using [<sup>14</sup>C] ring-labeled diazinon. Sheep must be treated with an appropriate formulation at 0.52 lb ai/100 gal or an amount that will result in sufficient residues in the tissues and milk for characterization. A maximum number of applications and a minimum interval between applications must be proposed,

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

and the required study must reflect the maximum use regiment of treatments thus permitted. Poultry studies are required utilizing ring-labeled [<sup>14</sup>C] diazinon administered orally. Oral administrations for ruminant and poultry studies must be made for at least 3 consecutive days. For all studies, animals must be sacrificed within 24 hours of cessation of dosing. Milk and eggs must be collected twice daily throughout the duration of the study. Residues must be characterized in muscle, fat, kidney, liver, milk, and eggs. All studies must be conducted utilizing sufficiently high doses to permit complete characterization of residues in these commodities.

Tissues of [<sup>14</sup>C] diazinon-dosed animals must also be analyzed by methods approved for enforcement to verify whether compounds of toxicological concern have been adequately characterized.

- 4/ Additional methods, validation data, and residue data (for representative commodities) are required if the metabolism studies requested in 171-4 (Nature of the Residue in Plants and Nature of the Residue in Animals) indicate that additional metabolites constitute residues of toxicological concern in plants or animals.
- 5/ All of the plant residue and animal feeding data required under this Standard must be accompanied by information pertaining to the conditions and duration of sample storage prior to residue analysis and on the stability of diazinon under the storage conditions used. If the required metabolism data indicate the presence of residues of toxicological concern in plant and animal commodities, data depicting the stability of such residues in storage are also required.

To support crop residue data, storage stability studies must be conducted on both weathered samples and fortified frozen samples of one representative crop from each crop grouping (40 CFR §180.34) on which registered uses of diazinon exist. Analyses of each crop must be conducted over a time period that includes the time interval that the raw agricultural commodity (RAC) is held in frozen storage prior to the crop residue analysis. To support residue data on processed commodities, fortified storage stability data are required for all processing studies submitted to the Agency. Analyses must be conducted over a time period that includes the frozen storage RAC prior to processing and each processed commodity prior to the residue analysis. Acceptable protocols must be submitted to the Agency ninety (90) days after receipt of this Notice. The protocols must be approved by the Agency prior to initiating the studies.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

(a) Storage stability data using weathered samples. Data are required on the parent compound in which crop samples field treated with a typical end-use product are frozen immediately upon harvesting. The integrity of the samples must be maintained by freezing. The samples must be analyzed for diazinon on the day they arrive at the analytical laboratory, and then stored frozen and analyzed periodically for diazinon during the time intervals specified in the Agency approved protocols.

(b) Storage stability data using fortified samples. Data are required on diazinon and metabolites of concern in which a group of untreated samples of RACs and process crops are fortified (spiked) with only diazinon (pure active ingredient) and other groups are fortified individually with each metabolite of concern. Immediately after fortification, the samples fortified with diazinon must be analyzed for diazinon and samples fortified with other metabolites of concern must be analyzed for only the metabolite with which the sample was fortified. Sample integrity must be maintained by freezing, and analyses for diazinon and metabolites must be conducted during the time intervals specified in the Agency approved protocols.

(c) Storage stability data for livestock/poultry feeding studies. If cattle and poultry feeding studies are required (see footnote 111), fortified storage stability studies will be required on all animal commodities (i.e., tissues, milk and eggs) for which residue data are submitted to the Agency. Analyses must be conducted over a time period that includes the time interval that each commodity is held in frozen storage prior to residue analyses.

6/ Residue data are required to determine diazinon residues of concern in or on beets resulting from the following full-season application schedule: i) preplant broadcast soil application of a WP, EC, and G formulation (each in separate tests) at 10 lb ai/A; and ii) multiple foliar applications of a WP, EC, and D formulation (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum number of applications per season or maximum seasonal use rate for the label, and the required data must be produced using these maximums. Separate tests must be conducted using ground and aerial equipment. The tests must be conducted in Oregon, Texas, California, New York, and Wisconsin.

7/ Residue data are required to determine diazinon residues of concern in or on carrots resulting from the following full-season application schedule: 1) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 2 lb ai/A at planting time; and ii) foliar application of a D, WP, and EC formulation (each in separate tests) at 0.5 lb ai/A; carrots must be harvested 10 days after the last application if multiple treatments are used (see below). In additional tests, carrots must be harvested 14 days following the last foliar

Table A  
Generic Data Requirements for Diazinon (cont'd)

\$158.240 Residue Chemistry Footnotes (cont'd)

application of 0.5% PrL formulation. Separate tests must be made using ground and aerial equipment. The registrant must propose a maximum number of foliar and postemergence broadcast soil applications allowed per season or maximum seasonal use rate for the label and the required data must be produced using these maximums. Separate tests must be conducted using ground and aerial equipment. Tests must be conducted in California, Michigan, Texas, and Washington.

- 8/ Residue data are required to determine diazinon residues of concern in or on parsnips. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on parsnips, or b) indicate support of the use on radishes and turnips and request that the required data for those use patterns be used to support the use on parsnips.
- 9/ Residue data are required to determine diazinon residues of concern in or on potatoes resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, EC, and WP formulation (each in separate tests) at 6 lb ai/A; ii) at plant soil (band) application of a G formulation at 3 lb ai/A; and, iii) multiple foliar applications (by ground and in separate tests, aerial equipment) of an EC and WP formulation (each in separate tests) at 0.083 oz/gal and (in separate tests) a D formulation at 2 lb ai/A. Potato samples must be harvested 35 days after the last foliar application. The registrant must propose a maximum permissible number of foliar applications per season or maximum seasonal use rate for the label, and the require data must be produced using these maximums. Tests should be conducted in Idaho, Washington, Maine, California, North Dakota, Wisconsin, and Colorado.
- 10/ Residue data are required to determine diazinon residues in granules, wet and dried peels, and dried chips from potatoes bearing measurable weathered residues. If residues concentrate in either of these processed commodities, appropriate food/feed additive tolerances must be proposed.
- 11/ Residue data are required to determine diazinon residues of concern in or on radishes resulting from the following full-season application schedule: i) preplant broadcast soil application of G, EC, and WP formulation (each in separate tests) at 10 lb ai/A; ii) soil application of a G, EC, and WP formulation (each in separate tests) at 0.7 oz/1000 feet of row at-planting; iii) transplant drench application of a WP and EC formulation (each in separate tests) at 2 lb ai/100 gal/A; and iv) foliar application of a WP and EC formulation at 0.5 lb ai/A, and a D formulation at 1.6 lb ai/A (each in separate tests). Radishes must be harvested 10 days after the last application of each treatment. In separate tests, radishes must be harvested 14 days after the last foliar application of the

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

0.5% PrL; separate tests must be conducted using ground and aerial equipment. The registrant must propose a maximum seasonal use rate of maximum number of treatments per season, for preplant broadcast soil, soil, foliar, and transplant water applications, for the label and the required data must be produced using these maximums. Tests must be conducted in California, Florida, and Michigan.

- 12/ Although a tolerance of 0.75 ppm has been established for residues of diazinon in or on rutabagas, there are no current federally registered products with this use pattern. No data are available to assess the adequacy of the tolerance for diazinon residues in or on rutabagas. The registrant may propose a use for diazinon on rutabagas and must submit appropriate supporting data. If the proposed use for rutabagas is similar to the registered uses of diazinon on carrots, radishes, or parsnips, then data required in support of tolerances for these commodities may be translated to rutabagas. If such use directions and supporting data are not submitted, the Agency will propose revocation of this tolerance through the Tolerance Revocation Program.
- 13/ Residue data are required to determine diazinon residues of concern in or on sugar beet roots resulting from the following full-season application schedule: i) preplant, broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 4 lb ai/A; ii) soil (band) application of a G formulation at 2 lb ai/A at-planting, and at 1.5 lb ai/A early preemergence; and iii) multiple foliar applications (by ground, and in separate tests, aerial equipment) of a WP, and in separate tests, an EC formulation at 0.5 lb ai/A. The registrant must propose a maximum foliar use rate or maximum number of foliar treatments per season for the label, and the required data must be produced using these maximums. These tests must be conducted in Idaho, Minnesota, California, North Dakota, and Michigan, and must reflect a 0-day preharvest interval.
- 14/ Residue data are required to determine diazinon residues in dehydrated pulp, molasses, and refined sugar from sugar beets bearing measurable weathered residues. Exaggerated rates of application may be necessary to achieve such residue levels. If residues are found to be concentrate in any of the processed commodities, then appropriate food/feed additive tolerances must be proposed.
- 15/ Residue data are required to determine diazinon residues of concern in or on sweet potatoes. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested; or b) indicate support of the use on potatoes and request that the required data for that use pattern be used to support the use on sweet potatoes.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 16/ Residue data are required to determine diazinon residues of concern in or on turnip roots resulting from the following full-season application schedule: i) preplant broadcast soil application of G, WP, and EC formulations (each in separate tests) at 10 lb ai/A; ii) at-plant soil application of a G, EC, and WP formulation (each in separate tests) at 0.7 oz/1000 feet of row at-planting; iii) transplant water application of a WP and EC formulation (each in separate tests) at 0.5 lb ai/A; and iv) foliar application of a WP and EC formulation at 0.5 lb ai/A, a 0.5% PrL, and a D formulation at 1.6 lb ai/A (each in separate tests). Turnips must be harvested 10 days after the last foliar application of each treatment. Tests must be conducting using ground and aerial equipment. The registrant must propose a maximum seasonal use rate or maximum number of foliar treatments per season for the label, and the required data must be produced using these maximums. Tests must be conducted in Tennessee, Florida, or Georgia and Arizona, and/or California.
- 17/ Residue data are required to determine diazinon residues of concern in or on garden beet tops harvested following a full-season application schedule: i) preplant broadcast soil application of a WP, EC, and G formulation (each in separate tests) at 10 lb ai/A; and ii) foliar applications of a WP, EC, and D formulation (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in Oregon, Texas, California, New York, and Wisconsin.
- 18/ Although a tolerance of 0.7 ppm has been established for residues of diazinon in or on red chicory tops (also known as radicchio) there are no current federally registered products with directions for use on chicory. No data are available to assess the adequacy of the tolerance for diazinon residues in or on red chicory tops. The registrant may propose a use for diazinon on chicory and must submit appropriate supporting data. If such use directions and supporting data are not submitted, the Agency will propose revocation of this tolerance through the Tolerance Revocation Program.
- 19/ Residue data are required to determine diazinon residues of concern in or on sugar beet tops resulting from the following full-season application schedule: i) preplant, broadcast soil application with a G, WP, and EC formulation (in separate tests) at 4 lb ai/A; ii) soil application at-planting time (band) with a G formulation a 2 lb ai/A; iii) foliar applications (by ground, and in separate tests, aerial equipment) with a G formulation at 0.5 lb ai/A; and iv) early postemergent soil application at 1.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of foliar applications per season for the label, and the required data must be produced using these maximums. Test must be conducted in Idaho, Minnesota, California, North Dakota, and Michigan, and must incorporate a 0-day PHI.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 20/ Residue data are required to determine diazinon residues of concern in or on turnip tops resulting from the following full-season application schedule: i) preplant broadcast soil application of G, WP, and EC formulations (each in separate tests) at 10 lb ai/A; ii) soil application of a G, EC, and WP formulation (each in separate tests) at 0.7 oz/1000 feet of row at-planting; iii) transplant water application of a WP and EC formulation (each in separate tests) at 0.5 lb ai/A; and iv) foliar application of a WP and EC formulation at 0.5 lb ai/A, a 0.5% PrL, and a D formulation at 1.6 lb ai/A (each in separate tests). Turnips must be harvested 10 days after the last foliar application of each treatment. Tests must be conducted using ground and aerial equipment. The registrant must propose a maximum seasonal use rate or maximum number of foliar applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, Texas, Arizona, Georgia, Florida, and Tennessee.
- 21/ Residue data are required to determine diazinon residues of concern in or on dry bulb and green onions following a full-season application schedule that includes: i) preplant broadcast soil incorporation of a G, WP, and EC (each in separate tests) at 4 lb ai/A; ii) at-plant, in-furrow soil application of a D, EC, G, and WP (each in separate tests), at 1.4, 1, 1, and 1 lb ai/A, respectively; and iii) multiple foliar applications (by ground, and in separate tests, aerial equipment) of a D at 1.2 lb ai/A, a WP at 0.5 lb ai/A, and an EC at 0.5 lb ai/A (each in separate tests). Tests must reflect a 10-day PHI. The registrant must propose a maximum seasonal use rate or maximum number of foliar and preplant applications per season for the label, and the required data must be produced using these maximums. For green onions, tests must be conducted in Arizona, California, and Texas; for dry onions, tests must be conducted in California, New York, Oregon, and Texas. In addition, data are required for one additional Allium spp. group member.
- 22/ Residue data are required to determine diazinon residues of concern in or on untrimmed celery resulting from the following full-season application schedule: 1) preplant broadcast soil application of a G, WP, and EC (each in separate tests) at 4 lb ai/A; and ii) multiple foliar applications (by ground and, in separate tests, aerial equipment) of a WP, EC, and D (each in separate tests) at 0.5 lb ai/A. The required tests must incorporate a 10-day PHI. The registrant must propose a maximum seasonal foliar use rate or maximum number of foliar treatments per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, Florida, and Michigan.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 23/ Residue data are required to determine diazinon residues of concern in or on endive. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either a) request a determination of the specific formulations, rates, and application schedule to be tested on endive; or b) indicate support of the use on lettuce and request that the required data for that use pattern be used to support the use on endive.
- 24/ Residue data are required to determine diazinon residues of concern in or on untrimmed lettuce (head and leaf varieties) resulting from the following full-season schedule; i) preplant broadcast soil application of a G, WP, and EC (each in separate tests) at 10 lb ai/A; and ii) multiple foliar applications (by ground and, in separate tests, aerial equipment) of a WP, D, and EC formulation (each in separate tests) at 0.5 lb ai/A. Required tests must incorporate a 10-day PHI. The registrant must propose a maximum seasonal use rate or maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, Arizona, and Florida.
- 25/ Residue data are required to determine diazinon residues of concern in or on parsley resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC (each in separate tests) at 4 lb ai/A; and ii) multiple foliar applications (by ground and aerial equipment) of a D formulation at 1.6 lb ai/A. These tests must incorporate a 12-day PHI. The registrant must propose a maximum seasonal foliar use rate or maximum number of foliar treatments per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, Florida, New Jersey, and Texas.
- 26/ Residue data are required to determine diazinon residues of concern in or on spinach resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC (each in separate tests) at 4 lb ai/A; and ii) multiple foliar applications (by ground and, in separate tests, aerial equipment) of a WP, EC, and D (each separate tests) at 0.5 lb ai/A. The required tests must incorporate a 10-day PHI. The registrant must proposed a maximum seasonal foliar use rate or maximum number of foliar treatments per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California and Texas.



Table A  
Generic Data Requirements for Diazinon (cont'd)

\$158.240 Residue Chemistry Footnotes (cont'd)

- 27/ Residue data are required to determine diazinon residues of concern in or on swiss chard. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either a) request a determination of the specific formulations, rates, and application schedule to be tested on swiss chard; or b) indicate support of the use on parsley and request that the required data for that use pattern be used to support the use on swiss chard.
- 28/ Residues data are required to determine diazinon residues of concern in or on broccoli harvested 5 days after completion of the following full-season treatment schedule: i) preplant soil broadcast incorporation of a G, WP, and EC (each in separate tests) at 4 lb ai/A; ii) at-plant soil application of a G, WP, and EC (each in separate tests) at 0.7 oz ai/1000 ft of row; iii) transplant drench treatment with an EC and a WP (each in separate tests) at 0.5 lb ai/100 gal, applied at 300 gal/A (for an effective use rate of 1.5 lb ai/A); and iv) multiple foliar applications (by ground and in separate tests, by aerial equipment) of a D at 1.6 lb ai/A, and a WP and an EC (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of foliar treatments per season, and the required data must be produced using these maximums. Tests must be conducted in California Texas, and Oregon.

87 Residue data are also required to support the Special Local Need (SLN) registration on broccoli. Tests in California are required using before-transplant foliar application(s) (by ground and air in separate tests) of aWP at 3 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of treatments per year for the SLN label, and the required data must be produced using these maximums and a 5-day PHI. Revised SLN labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of the SLN registration in California that permits this use.

- 29/ Residue data are required to support the registered uses of diazinon on Brussels sprouts. If a crop group tolerance supported by data is not obtained, then residue data are required to determine diazinon residues of concern in or on Brussels sprouts harvested 7 days after completion of the following full-season treatment schedule: i) preplant soil broadcast incorporation of a G, WP, and EC (each in separate tests) at 4 lb ai/A ii) at-plant soil application of a G, WP, and EC (each in separate tests) at 0.7 oz ai/1000 ft of row; iii) transplant drench treatment with an EC and a WP (each in separate tests) at 0.5 lb ai/100 gal, applied at 300 gal/A (for an effective use rate of 1.5 lb ai/A); and iv) multiple foliar applications (by ground and, in separate tests, by aerial equipment) of a D at 1.6 lb ai/A, and a WP and an EC (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of foliar applications per season for the

Table A  
Generic Data Requirements for Diazinon (cont'd)

\$158.240 Residue Chemistry Footnotes (cont'd)

label, and the required data must be produced using these maximums. Tests must be conducted in California and New York.

Residue data are also required to support the SLN registration on Brussels sprouts. Tests in California are required using before-transplant foliar application(s) (by ground and air in separate tests) of a WP at 3 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of soil treatments per year for the label, and the required data must be produced using these maximums and a 7-day PHI. Revised SLN labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of the SLN registration in California that permits this use.

- 30/ Residue data are required to determine diazinon residues of concern in or on cabbage receiving the following full-season application schedule: i) preplant broadcast soil incorporation of a G, WP, and EC at 10 lb ai/A (each in separate tests); ii) at-plant soil application of a G, WP, and EC (each in separate tests) at 0.07 oz ai/1000 ft of row; iii) transplant water drench application of a WP and an EC (each in separate tests) at 0.5 lb ai/100 gal, applied at 300 gal/A; and iv) multiple foliar applications of a D at 1.6 lb ai/A, a WP at 0.5 lb ai/A, and an EC at 0.5 lb ai/A (each in separate tests). These tests must incorporate a PHI of 7 days, and must be conducted in California, Florida, New York, Texas, and Wisconsin.

Residue data are also required to support the SLN registrations on cabbage. Tests in California are required using before-transplant foliar application(s) (by ground and air in separate tests) of a WP at 3 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of soil treatments per year for the SLN label, and the required data must be produced using these maximums and a 7-day PHI. Revised SLN labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of the SLN registration in California that permits this use.

- 31 Residue data are required to support the registered uses of diazinon on cauliflower. If a crop group tolerance supported by data is not obtained, then residue data are required to determine diazinon residues of concern in or on cauliflower harvested 5 days after completion of the following full-season treatment schedule: i) preplant soil broadcast incorporation of a G, WP, and EC (each in separate tests) at 4 lb ai/A; ii) at-plant soil application of a G, WP, and EC (each in separate tests) at 0.7 oz ai/1000 ft of row; iii) transplant drench treatment with an EC and a WP (each in separate tests) at 0.5 lb ai/100 gal, applied at 300 gal/A (for an

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

effective use rate of 1.5 lb ai/A); and iv) multiple foliar applications (by ground and in separate tests, by aerial equipment) of a D at 1.6 lb ai/A, and a WP and an EC (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of foliar applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, New York, Oregon, and Texas.

Residue data are also required to support the SLN registration on cauliflower. Tests in California are required using before-transplant foliar application(s) (by ground and air in separate tests) of a WP at 3 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of soil treatments per year for the label, and the required data must be produced using these maximums and a 5-day PHI. Revised SLN labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of the SLN registration in California that permits this use.

32/ Residue data are required to support the registered uses of diazinon on collards. If a crop group tolerance supported by data is not obtained, then residue data are required to determine diazinon residues of concern in or on collards harvested 10 days after completion of the following full-season treatment schedule: i) preplant soil broadcast incorporation of a G, a WP, and an EC (each in separate tests) at 4 lb ai/A; ii) at-plant soil application of a G, a WP, and an EC (each in separate tests) at 0.7 oz ai/1000 ft of row; iii) transplant drench treatment with an EC and a WP (each in separate tests) at 0.5 lb ai/100 gal, applied at 300 gal/A (for an effective use rate of 1.5 lb ai/A); and iv) multiple foliar applications (by ground and, in separate tests, by aerial equipment) of a D at 1.6 lb ai/A, and a WP and an EC (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in Georgia, Florida, and Virginia.

Residue data are also required to support the SLN registration on collards. Tests in California are required using before-transplant foliar application(s) (by ground and air in separate tests) of a WP at 3 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of soil treatments per year for the label, and the required data must be produced using these maximums and a 10-day PHI. Revised SLN labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of the SLN registration in California that permits this use.

Table A  
Generic Data Requirements for Diazinon (cont'd)

\$158.240 Residue Chemistry Footnotes (cont'd)

- 33/ Residue data are required to support the registered uses of diazinon on kale. If a crop group tolerance supported by data is not obtained, then residue data are required to determine diazinon residues of concern in or on kale harvested 10 days after completion of the following full-season treatment schedule: i) preplant soil broadcast incorporation of a G, a WP, and an EC (each in separate tests) at 4 lb ai/A; ii) at-plant soil application of G, a WP, and an EC (each in separate tests) at 0.7 oz ai/1000 ft of row; iii) transplant drench treatment with an EC and a WP (each in separate tests) at 0.5 lb ai/100 gal, applied at 300 gal/A (for an effective use rate of 1.5 lb ai/A); and iv) multiple foliar applications (by ground and, in separate tests, by aerial equipment) of a D at 1.6 lb ai/A, and a WP and an EC (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in New York and Virginia.

Residue data are also required to support the SLN registration on kale. Tests in California are required using before-transplant foliar application(s) (by ground and air in separate tests) of a WP at 3 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of soil treatments per year for the label, and the required data must be produced using these maximums and a 10-day PHI. Revised SLN labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of the SLN registration in California that permits this use.

- 34/ Residue data are required to determine diazinon residues of concern in or on mustard greens harvest 10 days after completion of the following full-season treatment schedule: i) preplant soil broadcast incorporation of a G, a WP, and an EC (each in separate tests) at 4 lb ai/A; ii) at-plant soil application of a G, a WP, and an EC (each in separate tests) at 0.7 oz ai/1000 ft of row; iii) transplant drench treatment with an EC and a WP (each in separate tests) at 0.5 lb ai/100 gal, applied at 300 gal/A (for an effective use rate of 1.5 lb ai/A); and iv) multiple foliar applications (by ground and, in separate tests, by aerial equipment) of a D at 1.6 lb ai/a, and a WP and an EC (each in separate tests) at 0.5 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of foliar applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in Arizona, California, Florida, North California, and Texas.

Residue data are also required to support the SLN registration on mustard greens. Tests in California are required using before-transplant foliar application(s) (by ground and air in separate tests) of a WP at 3 lb ai/A. The registrant must propose a maximum seasonal use rate or maximum number of soil treatments per year for the label, and the required data must be produced using these maximums and a 10-day PHI. Revised SLN labeling must be

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

submitted that specifies the total number of applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of the SLN registration in California which permits this use.

- 35/ Residue data are required to determine diazinon residues of concern in or on beans, including lima and snap beans, resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 10 lb ai/A; and ii) multiple foliar applications of a WP and an EC formulation (in separate tests) at 0.75 lb ai/A, and a D formulation (in separate tests) at 1.4 lb ai/A. Beans must be harvested 7 days after the last foliar application. Tests must be conducted using ground, and in separate tests aerial equipment. The registrant must propose a maximum seasonal use rate or maximum number of applications per season for the label, and the required data must be produced using these maximums. Snap bean tests must be performed in Wisconsin, New York, Oregon, Florida, and Michigan. Tests with lima beans must be conducted in California, Delaware, Wisconsin, and Illinois.
- 36/ Residue data are required to determine diazinon residues of concern in or on cowpeas. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on cowpeas, or b) indicate support of the use on peas and soybeans and request that the required data for those use patterns be used to support the use on cowpeas.
- 37/ Residue data are required to determine diazinon residues of concern in or on peas (succulent and dry) following a full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (in separate tests) at 10 lb ai/A; and ii) multiple foliar applications (reflecting use of both ground and aerial equipment) of a D and WP formulation (in separate tests) at 0.5 lb ai/A. Samples must be harvested on the day of the final foliar treatment. Tests must be conducted in Wisconsin, Washington, and Minnesota. The registrant must propose a maximum seasonal use rate or maximum number of foliar and soil applications per season for the label, and the required data must be produced using these maximums.

Residue data are required to determine residues of concern in or on dried peas and peas with pods (succulent) harvested 7 days following the last of four foliar applications of a D formulation at 1.35 lb ai/A. Tests must be conducted in California. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. CA-800105, which permits this use in California.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

Residue data are required to determine residues of concern in or on peas (succulent and dried) harvested after the last of three soil drench applications (at 14- to 16-day intervals) with the 4 lb/gal EC at 5 lb ai/A. Tests must be conducted in California using ground equipment. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. CA-830017, which permits this use in California.

- 38/ Residue data are required to determine diazinon residues of concern in or on soybeans resulting from the following treatment regimen: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests), at 4 lb ai/A. Tests must be conducted using both ground, and in separate tests, aerial equipment. Tests must be conducted in Arkansas, North Dakota, Texas, Kansas, and Missouri.
- 39/ Residues must be determined in meal, hulls, soapstock, crude oil, and refined oil processed from soybeans bearing measurable weathered residues. If residues concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.
- 40/ Residue data are required to determine diazinon residues of concern in or on lima and snap beans vines and hay resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 10 lb ai/A; and ii) multiple foliar applications of a WP and EC formulation (in separate tests) at 0.75 lb ai/A, and a D formulation at 1.4 lb ai/A. Bean hay must be harvested 4 days after the last foliar application. Tests must be conducted using ground, and in separate tests, aerial equipment. The registrant must propose a maximum seasonal use rate or maximum number of applications per season and the interval between these applications for the label, and the required data must be produced using these maximums. Snap bean tests must be conducted in Wisconsin, New York, Oregon, Florida, and Michigan. Tests with lima beans must be conducted in California, Delaware, Wisconsin, and Illinois.
- 41/ Residue data are required to determine diazinon residues of concern in or on cowpea vines and hay. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on cow pea vines and hay; or b) indicate support of the use on soybean hay and straw and request that the required data for those use patterns be used to support the use on cowpea vines and hay.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

42/ Residue data are required to determine diazinon residues of concern in or on peas (succulent and dry) following a full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (in separate tests) at 10 lb ai/A; and ii) multiple foliar applications (reflecting use of both ground and aerial equipment) of a D and WP formulation (in separate tests) at 0.5 lb ai/A. Samples must be harvested on the day of final foliar treatment. Tests must be conducted in Wisconsin, Washington, Minnesota, and Oregon. Studies must incorporate a 4-day PHI. A pregrazing interval for vines and hay must be proposed. The registrant must propose a maximum number of foliar applications per season for the label, and the required data must be produced using the maximums.

Residue data are required to determine residues of concern in or on pea vines and hay harvested 7 days following the last of four foliar applications of a D formulation at 1.35 lb ai/A. Tests must be conducted in California, and must incorporate a 7-day PHI. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. CA-800105, which permits this use in California.

Residue data are also required to determine residues of concern in or on pea vines and hay harvested after the last of three soil drench applications at 14-day to 16-day intervals with the 4 lb/gal EC at 5 lb ai/A. Tests must be conducted in California. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. CA-830017, which permits this use in California.

43/ The registrant must propose tolerances for soybean straw and hay, which are RACs of soybean and submit appropriate supporting data, or established feeding/grazing restrictions. Data depicting diazinon residues of concern in or on soybean forage resulting from the following treatment regimen: preplant broadcast soil application of a G, a WP, and an EC formulation (each in separate tests), at 4 lb ai/A. Tests must be conducted using both ground, and in separate tests, aerial equipment. Tests must be conducted in Iowa, Illinois, Minnesota, Indiana, Mississippi, and Ohio.

44/ Residue data are required to determine diazinon residues of concern in or on peppers treated with the following full-season application regimen: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 4 lb ai/A, and ii) multiple foliar applications of a D formulation at 1.6 lb ai/A, and in separate tests, a WP and an EC formulation at 0.267 lb ai/A. Peppers must be harvested 5 days following the last in a series of foliar applications. Tests must be conducted using ground, and in separate tests, aerial equipment. The registrant must propose a maximum use rate or maximum number of applications per season for the label, and the required data must be produced using these maximums. The required tests must support that number.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

The tests must be conducted in Florida, California, Texas, North Carolina, and New Jersey.

- 45/ Residue data are required to determine diazinon residues of concern in or on tomatoes treated with the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 10 lb ai/A; ii) multiple foliar applications of a D formulation at 1.6 lb ai/A, and in separate tests, a WP and an EC formulation at 0.75 lb ai/A. Tomato samples must be harvested 3 days after the last dust application and 1 day after the last spray application. Tests must be conducting using ground, and in separate tests, aerial equipment; and iii) broadcast soil application of a D formulation, and in separate tests, a G formulation at 1 lb ai/A. For soil and foliar applications, the registrant must propose a maximum seasonal use rate or maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California and Florida.

94 Residue data are also required to support the SLN registrations for greenhouse-grown tomatoes. Residue data are required to determine diazinon residues of concern in or on greenhouse-grown tomatoes harvested 3 days following the last of multiple foliar tests, applied 7 to 10 days apart, using the 50% WP formulation (to be tested in North California), and the 48% EC formulation (to be tested in Ohio) at 8 oz product/100 gal. In addition, multiple foliar tests must be conducted in California on greenhouse-grown tomatoes harvested 1 day following the last application at 1 1/8 tbsp of 48% EC product/1000 sq ft.

- 46/ Residue data are required to determine diazinon residues of concern in or on tomato puree, catsup, and juice processed from tomatoes bearing measurable weathered residues. Exaggerated rates of application may be necessary to achieve such residue levels.
- 47/ Residue data are required to determine diazinon residues of concern in or on cucumbers 7 days following the last of multiple foliar applications with a D formulation at 1.6 lb ai/A and a WP and EC (each in separate tests) at 0.5 lb ai/A. All tests must include one preplant broadcast application of a WP, and EC, a G, and a D formulation (separate tests for each) at 4 lb ai/A. The registrant must propose a maximum seasonal foliar use rate, or a maximum number of foliar applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, Florida, Georgia, Michigan, North Carolina, South Carolina, Texas, and Virginia.



Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 48/ Tests depicting diazinon residues of concern in or on melons harvested 3 days after the last of multiple foliar applications of a D formulation at 1.4 lb ai/A and of WP and EC formulations at 0.75 lb ai/A (each in separate tests). Each of the above tests must include a preplant broadcast soil application of a WP, a D, a G, and an EC formulation (separate tests for each) at 4 lb ai/A. The registrant must propose a maximum foliar seasonal use rate, or a maximum number of foliar applications per season for the label, and the required data must be produced using these maximums. Watermelon tests must be conducted in California, Florida, Georgia, and Texas. Cantaloupe tests should be performed in California and Texas.
- 49/ Residue data are required to determine diazinon residues of concern in or on summer squash resulting from the following full-season application schedule: i) multiple foliar applications of a D formulation at 1.4 lb ai/A and of a WP and an EC formulation (each in separate tests), at 0.75 lb ai/A; and ii) preplant broadcast soil application of a WP, D, G, and an EC formulation (separate test for each) at 4 lb ai/A. The registrant must propose a maximum foliar seasonal use rate, or a maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, Florida, Georgia, Massachusetts, Michigan, New Jersey, New York, North Carolina, and Texas.
- 50/ Residue data are required to determine diazinon residues of concern in or on winter squash. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on winter squash; or b) indicate support of the use on melons and request that the required data for that use pattern be used to support the use on winter squash.
- 51/ Tests are required depicting residues of concern in or on lemons, oranges, and grapefruit harvested 21 days following the last of: multiple foliar applications with a D formulation at 8 lb ai/A, and WP and EC formulations (in separate tests) at 10 lb ai/A (1 lb ai/100 in 1000 gal/A). The registrant must propose a maximum foliar seasonal use rate or a maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests on oranges and grapefruit should be conducted in Florida. Tests on lemons should be conducted in California.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

Residue data are required to support the SLN registration in Florida. Residue data are required to determine diazinon residues of concern in or on grapefruit, oranges, and lemons harvested 21 days following the last of multiple foliar applications with a 4 lb/gal EC formulation at 0.5 lb ai/100 gal water (applied at  $\leq$  1000 gal/A). The test must be conducted in Florida. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. FL-770036, which permits this use in Florida.

Residue data are required to support the SLN registrations in California. Residue data are required to determine diazinon residues of concern in or on grapefruit, oranges, and lemons harvested 21 days following the last of multiple applications with a 14% G formulation, broadcasted and incorporated at the maximum rate until the 19.6 lb ai/A per year limit has been achieved. Application of a 14% G formulation must be tested with both ground, and in separate tests, aerial equipment (broadcast only). The tests must be conducted in California. If the data support the tolerance, the registrant should amend the SLN labels so that all include the 19.6 lb ai/A per year limit and amend the label for the 5% G formulation to include the same maximum permitted use per season as the 14% G formulation, or else propose a maximum number of applications. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. CA-770033 (5% G), CA-760014 (14% G), and CA-810066 (14% G) which permit this use in California.

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- 52/ Residue data are required to determine residues in citrus oil, molasses, and juice processed from whole citrus fruits bearing measurable weathered residues. Exaggerated application may be necessary to achieve such residue levels. If residues are found to concentrate in any of the processed commodities, appropriate food/feed additive tolerances must be proposed.
- 53/ Residue data are required to determine diazinon residues of concern in or on apples harvested 14 days after the last of eight foliar applications at 10-day intervals of i) a D formulation at 4 lb ai/A (using ground and aerial equipment in separate tests); ii) a WP and an EC formulation, in separate tests, at 2.8 lb ai/A using both aerial and low-volume ground equipment; and iii) a WP formulation at 4 lb ai/A using high-volume ground equipment (0.5 lb ai/100 gal). Trials must be conducted in California, Michigan, New York, Pennsylvania, Washington, and Virginia.

Residue data are also required to support the SLN registration in California. Residue data are required to determine residues of concern in or on apples treated according to the above treatment regimens, plus multiple soil drench applications of the 4 lb/gal EC formulation at 5 lb ai/A. This test must be conducted in California. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. CA-830017, which permits the soil drench method of California.

Table A  
Generic Data Requirements for Diazinon (cont'd)

\$158.240 Residue Chemistry Footnotes (cont'd)

- 54/ Residue data are required to determine diazinon residues in wet and dry pomace, and juice processed from apples bearing measurable weathered residues. Should residues concentrate in the processed apple products, the registrant must propose appropriate food/feed additive tolerances.
- 55/ Residue data are required to determine diazinon residues of concern in or on pears. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on pears; or b) indicate support of the use on apples and request that the required data for that use pattern be used to support the use on pears. The registrant should note that translated data may not be used to support a group tolerance.
- 56/ Residue data are required to determine diazinon residues of concern in or on apricots. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on apricots; or b) indicate support of the use on nectarines and request that the required data for that use pattern be used to support the use on apricots.

In addition, data are lacking to support the existing SLN registrations in California which permit use of the 50% WP, and 4 lb/gal and 48% EC formulations at rates less restrictive than the Federal registrations. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either a) request a determination of the specific formulations, rates, and application schedule to be tested on apricots, or b) electing to indicate support of the use of nectarines and request that the required data for that use pattern be used to support the use on apricots, or c) requesting voluntary cancellation of SLN Registration Nos. CA-810043, CA-810047 (foliar), and CA-830017 (soil drench) which permit these uses in California.

- 57/ Residue data are required to determine diazinon residues of concern in or on sweet and sour cherries 10 days following the last of five foliar applications of the following formulation (each in separate tests): i) an EC at 0.5 lb ai/100 gal; ii) a WP at 0.6 lb ai/100 gal; iii) a D at 4 lb ai/A; iv) the 40% WP at 4 lb ai/A by high-volume ground equipment; and v) the 40% WP at 2.8 lb ai/A by aircraft and low-volume ground equipment (each in separate tests). Tests must be conducted in California or Oregon, Michigan, and Washington.

Residue data are also required to support SLN registrations. The data must reflect diazinon residues of concern in or on cherry samples 10 days after i) the last of multiple foliar applications of the 50% WP formulation at 2 lb ai/A applied by aircraft in no less than 10 gal/A, and by ground in no less than 100 gal/A; and ii) three

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

applications 14 days apart of a 4 lb/gal EC or 48% EC formulation at 5 lb ai/A in 130 gal applied by ground as a soil drench in addition to the treatments described above. In the case of the 50% WP, the registrant must propose a maximum number of applications or a maximum seasonal use rate for the label, the required data must be produced using these maximums, and revised labeling must be submitted that specifies the maximum number of applications and the interval between these applications. All tests must be conducted in California. Alternatively the registrant may request voluntary cancellation of SLN Registration Nos. CA-810043, CA-830009, and CA-830017, which permit these uses in California.

58/ Residue data are required to determine diazinon residues of concern in or on nectarine samples 10 days following the last of multiple foliar applications with the following formulations (each in separate tests); i) a D at 4 lb ai/A; ii) the 40% WP at 4 lb ai/A applied by high-volume ground equipment, and, in separate tests, at 2.8 lb ai/A applied by aircraft; and iii) an EC at 0.5 lb ai/100 gal. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California.

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Residue data are also required to support SLN registrations. Residue data are required to determine diazinon residues of concern in or on nectarine samples receiving the following applications: i) a single application of the 14% G formulation at 2.8 lb ai/A applied both by ground and aircraft in separate tests; ii) multiple foliar applications of the 50 WP formulation at 2 lb ai/A applied by aircraft in no less than 10 gal/A, and in separate tests, by ground in no less than 100 gal/A; iii) three foliar applications 14 days apart of a 4 EC or 48% EC formulation at 5 lb ai/A in 130 gallons applied by ground as a soil drench; and iv) the treatments noted above. In the case of ii) the registrant must propose a maximum number of application so or a maximum seasonal use rate for the label, the required data must be produced using these maximums, and revised labeling must be submitted that specifies the maximum number of applications and the interval between these applications. Tests must be conducted in California. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. CA-810043, CA-830009, and CA-830017, which permit these uses in California.

59/ Residue data are required to determine diazinon residues of concern in or on peaches harvested 20 days after the last of multiple seasonal foliar applications with the following formulations (each in separate tests), by both air and ground application (in separate tests): i) the D formulation at 4 lb ai/A; ii) the EC formulation at both 0.5 lb ai/100 gal; and iii) the 40% WP formulation at both 2.8 lb ai/A applied by aircraft, and 4 lb ai/A applied by high-volume ground equipment in separate tests. Samples must be collected 20 days after the last treatment. The registrant must propose a maximum seasonal use rate or a maximum number of applications per season for the

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

label, and the required data must be produced using these maximums. Tests should be conducted in California, South Carolina, and Georgia.

Residue data are also required to support California SLN registrations. The data must identify residues of concern in or on peach samples after the above-noted treatments, plus the following applications: i) the 14% G formulation applied once at 2.8 lb ai/A by ground and aircraft in separate tests; ii) multiple foliar applications of the 50% WP formulation at 2 lb ai/A applied by aircraft in no less than 10 gal/A, and by ground in no less than 100 gal/A in separate tests; and iii) three applications (14 days apart) of a 4 lb/gal EC or 48% EC formulation at 5 lb ai/A in 130 gal applied by ground as a soil drench. In the case of ii), the registrant must propose a maximum number of applications or a maximum seasonal use rate for the label, the maximum number of applications and the interval between these applications. All tests must be conducted in California. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. CA-810043, CA-830009, and CA-830017, which permit these uses in California.

60/ Residue data are required to determine diazinon residues of concern in or on on plums and fresh prunes following multiple foliar applications with the following formulations, each in separate tests: i) a D at 4 lb ai/A; ii) an EC at 0.5 lb ai/100 gal; and iii) the 40% WP applied by aircraft at 2.8 lb ai/A, and by high-volume ground equipment at 4 lb ai/A (each in separate tests). Samples must be collected 10 days after the last treatment. The registrant must propose a maximum number of applications per season, or a maximum seasonal rate per acre for the label, and the require data must be produced using these maximums. Tests must be conducted in California.

Residue data are required to support California SLN registrations. The data must identify residues of concern in or on plum samples harvested 10 days after the following applications, in addition to those noted above: i) the 14% G formulation applied once at 2.8 lb ai/A both by ground equipment and aircraft in separate tests; ii) multiple foliar applications of the 50% WP formulation at 2 lb ai/A applied by aircraft, in no less than 10 gal/A, and by ground equipment, in separate tests, in no less than 100 gal/A; and iii) three applications (14 days apart) of a 4 lb/gal EC or 48% EC formulation at 5 lb ai/A in 130 gal, applied by ground as a soil drench. In the case of (ii), the registrant must propose a maximum number of applications or a maximum seasonal use rate for the label, the required data must be produced using these maximums, and revised labeling must be submitted which specifies the maximum number of applications and the interval between these applications. All tests must be conducted in California. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. CA-810043, CA-830009, and CA-830017, which permit these uses in California.

Table A  
Generic Data Requirements for Diazinon (cont'd)

\$158.240 Residue Chemistry Footnotes (cont'd)

- 61/ Residue data are required to determine diazinon residues of concern in or on dried prunes processed from plums bearing measurable weathered residues. If concentration of residues occurs during processing, an appropriate food/feed additive tolerance must be proposed.
- 62/ Residue data are required to determine diazinon residues of concern in or on blackberries. The registrant must contact the Agency, within the allowed ninety (90) day period for indicating intention to support this use, and either a) request a determination of the specific formulations, rates, and application schedule to be tested on blackberries; or b) indicate support of the use on raspberries and request that the required data for that use pattern be used to support the use on blackberries.
- 63/ Residue data are required to determine diazinon residues in or on blueberries 7 days following the last of multiple foliar applications of the EC, WP, and D formulations (one test for each) at 1 lb ai/A. The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season, for the label, and the required data must be produced using these maximums. Tests must be conducted in Michigan and New Jersey.
- 64/ Residue data are required to determine diazinon residues of concern in or on boysenberries. The registrant must contact the Agency within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on boysenberries; or b) indicate support of the use on raspberries and request that the required data for that use pattern be used to support the use of boysenberries.
- 65/ Tests depicting diazinon residues of concern in or on cranberries 7 days following the last of multiple foliar applications with both an EC and a WP formulation (a separate test for each) at 3 lb ai/A in 400 gal/A. The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season, for the label, the required data must be produced using these maximums. Tests must be conducted both in Massachusetts and Wisconsin.

Residue data are also required to support SLN registrations. Tests depicting diazinon residues of concern in or on cranberries harvested 7 days following the last of a treatment series that includes: i) foliar use of the EC and WP formulations as detailed above; AND ii) two broadcast applications, 7 to 10 days apart, of the 14% G formulation at 21 lb ai/A/application. Tests must be conducted in Massachusetts, New Jersey, and Oregon. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. MA-830005, MA-850001, MA-850002, NJ-840011, and OR-790056, which permit the use of 14% G diazinon on cranberries.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 66/ Residue data are required to determine diazinon residues of concern in or on dewberries. The registrant must contact the Agency within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on dewberries; or b) indicate support of the use on raspberries and request that the required data for that use pattern be used to support the use on dewberries.
- 67/ Residue data are required to determine diazinon residues in or on grapes 10 days following the last of multiple with the same interval requirements must be provided for EC and WP formulations (each in separate tests) applied with a wetting agent, and for the D formulation applied by aerial equipment. Separate tests must be conducted at 0.56 lb ai/A and a PHI of 7 days. The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season, for the label, and the required data must be produced using these maximums. Tests should be conducted in California.
- 68/ Residue data are required to determine diazinon residues in raisins, raisin waste, dry pomace, and grape juice processed from grapes bearing measurable weathered residues. Exaggerated rates may be necessary to obtain sufficient residues on the RAC. If the residues concentrate in any of these processed commodities, appropriate food/feed additive tolerances must be proposed.
- 69/ Residue data are required to determine diazinon residues of concern in or on loganberries. The registrant must contact the Agency within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request a determination of the specific formulations, rates, and application schedule to be tested on loganberries; or b) indicate support of the use on raspberries and request that the required data for that use pattern be used to support the use on loganberries.
- 70/ Residue data are required to determine diazinon residues of concern in or on raspberries receiving multiple foliar applications of a WP, and in separate an EC at 1 lb ai/A. The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season, for the label, and the required data must be produced using these maximums. Tests must reflect a 7-day PHI, and must be conducted in Oregon and Washington.
- Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 71/ Residue data are required to determine diazinon residues of concern in or on nature strawberries harvested 5 days following the last of multiple foliar applications with a D formulation at 1.2 lb ai/A and the EC and WP formulations at 1 lb ai/A (separate tests for each). The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season, for the label, and the required data must be produced using these maximums. Tests should be conducted in California.
- 72/ Residue data are required to determine diazinon residues of concern in or on almonds (nutmeats and hulls) resulting from the following full-season application schedule: i) multiple foliar applications of (in separate tests) a WP formulation at 2.8 lb ai/A using aircraft or low-volume ground equipment, in separate tests, a WP at 4 lb ai/A using high-volume ground equipment, an EC at 0.8 lb ai/100 gal (applied by ground and, in separate tests, by air), and a D formulation at 6 lb ai/A (applied by ground and aerial equipment in separate tests); and ii) dormant application (each in separate tests) of a WP formulation at 2.8 lb ai/A using aircraft or low-volume ground equipment (in separate tests), a WP at 4 lb ai/A using high volume ground equipment, and an EC formulation at 0.86 lb ai/gal (by ground and air in separate tests); and iii) multiple soil drench applications (at 14-day intervals) of an EC at 5 lb ai/A. The registrant must propose a maximum seasonal use rate for foliar applications for the label, and the required data must be produced using these maximums. Tests must be conducted in California.
- 73/ Residue data are required to determine diazinon residues of concern in or on filberts harvested on the day of the last of a series of multiple foliar applications (ending prior to husk split) of a WP and EC formulation (each in separate tests) at 2 lb ai/A, and a D formulation at 1.5 lb ai/A. Separate tests should reflect ground and aerial application of each formulation. These studies must be conducted in Oregon. A separate set of tests (to be conducted in California) must include multiple soil drench treatments with an EC formulation at 5 lb ai/A at 14-day intervals. The registrant must propose a maximum seasonal use rate for the label, and the required data must be produced using these maximums.
- 74/ Residue data are required to determine diazinon residues of concern in or on pecans receiving the following full-season application schedule: i) multiple foliar applications (by ground and air in separate tests) of a WP and an EC formulation (each in separate tests) at 3 lb ai/A, and (in separate tests), of a D formulation at a maximum rate which must be proposed by the registrant; and ii) multiple soil drench applications of a 4% EC formulation at 5 lb ai/A, to be repeated at 14-day intervals. Tests must incorporate a 0-day PHI. The registrant must propose a



Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

maximum seasonal use rate, or a maximum number of foliar applications per season, for the label, and the required data must be produced using these maximums. These studies must be conducted in Georgia, Texas, New Mexico, and Alabama.

- 75/ Residue data are required to determine diazinon residues of concern in or on walnuts receiving the following full-season application schedule: i) multiple dormant applications of the 0.33 lb/gal EC at 2.6 lb ai/200 gal/A; ii) multiple foliar applications (by ground, and in separate tests, by aerial equipment) of, in separate tests, a WP at 3 lb ai/A, an EC at 3 lb ai/A, and a D at 5 lb ai/A; and iii) multiple soil drench applications of an EC formulation at 5 lb ai/A, repeated at 14-day intervals. These studies must incorporate a 0-day PHI. The registrant must propose a maximum number of foliar applications per season for the label, and the required data must be produced using these maximums. Studies must be conducted in California.
- 76/ Residue data are required to determine diazinon residues of concern in or on field corn and in or on sweet corn (kernels plus cob with husks removed) from tests reflecting the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests), at 10 lb ai/A; ii) soil application of a G formulation at 2 lb ai/A, and a WP formulation at 2.5 oz/1000 ft of row, to be applied in a minimum of 5 gal water/A; iii) seed treatment application of a D and WP formulation (each in separate tests) at 1.67 oz/bu; and iv) multiple foliar applications of WP and EC formulation at 1.25 lb ai/A, and a G formulation at 2 lb ai/A (each in separate tests). In additional tests, corn samples must be harvested 10 days following the last of a series of foliar applications of a D formulation at 2 lb ai/A. Foliar applications must be made using ground equipment, and in separate tests, aerial equipment. The registrant must propose a maximum number of soil and foliar applications per season, and the required data must be produced using these maximums. Field corn tests must be conducted in Iowa, Illinois, Nebraska, Minnesota, Indiana, Ohio, and Wisconsin. Sweet corn tests must be conducted in Wisconsin, Washington, Oregon, Minnesota, and New York.
- 77/ Residue must be determined in crude and refined oil and milling products processed from field corn grain bearing measurable weathered residues. If residues are found to concentrate in any of these processed products, appropriate food/feed additive tolerances must be proposed.
- 78/ Residues data are required to determine diazinon residues of concern in or on sorghum grain resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 4 lb ai/A; ii) soil application of a G formulation at 2 lb ai/A at-planting or emergency (band); and iii) multiple foliar applications (by ground and, in separate tests, aerial equipment), of a W and EC formulation (each in separate tests) at 0.5 lb ai/A. Samples must be collected 7 days after the last

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

application. Aerial applications must be made in a minimum of 1 gal water/A and ground applications must be made in a minimum of 5 gal water/A. The registrant must propose a maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in Texas, Kansas, Nebraska, and Missouri.

- 79/ The milling study required for wheat will be translated to sorghum in order to determine whether food/feed additive tolerances will be needed for sorghum milling products.
- 80/ While there are no FIFRA section 3 registrations for use of diazinon in or on wheat, residue data are required to support SLN registrations. Residue data are required to determine diazinon residues of concern in or on wheat grain harvested after a single preplant broadcast soil application with the 4 lb/gal EC and the 14% G formulations at 2 lb ai/A, in separate tests. Tests must be conducted in Kansas, Montana, or North Dakota, and Texas or Oklahoma. Alternatively, the registrant may request voluntary cancellation of SLN Registrations Nos. KS-820018 (4 lb/gal EC), KS-820019 (14% G), OK-820005 (14% G), OK-830001 (14% G), and TX-820057 (4 lb/gal EC) which permit these uses.
- Residues data are also required to determine diazinon residues of concern in or on wheat grain harvested after a single preplant broadcast soil application with the 50% WP formulation at 2 lb ai/A. This test must be conducted in Kansas. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. KS-820017, which permits this use.
- 81/ A wheat milling study using grain bearing measurable weathered residues of diazinon is required. If residues are found to concentrate in any milling fraction, appropriate food/feed additive tolerances must be proposed.
- 82/ Additional residue data are required to support the established tolerances for corn forage and sorghum forage. A tolerance proposal must be submitted (and appropriate residue data provide) for corn fodder and forage and either sorghum fodder and forage, or wheat forage, hay, and straw.
- 83/ Residue data are required to determine diazinon residues of concern in or on sweet corn forage and corn fodder from tests using the following full-season application schedule: i) preplant broadcast soil application of a G, a WP, and an EC formulation (each in separate tests), at 10 lb ai/A; ii) soil application of a G formulation at 2 lb ai/A, and a WP formulation at 2.5 oz/1000 ft of row, to be applied in a minimum of 5 gal water/A; iii) seed treatment application of a D and WP formulation (each in separate tests) at 1.67 oz/bu; and iv) multiple foliar

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

applications of a WP and an EC formulation at 1.25 lb ai/A, and a G formulation at 2 lb ai/A (each in separate tests). In additional tests, corn samples must be harvested 10 days following the last of a series of foliar applications of a D formulation at 2 lb ai/A. Foliar applications must be made using ground equipment, and in separate tests, aerial equipment. Sweet corn tests must be conducted in Wisconsin, Washington, Oregon, Minnesota, and New York. The registrant must propose a maximum number of soil and foliar applications per season for the label, and the required data must be produced using these maximums.

Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications.

84/ Residue data are required to determine diazinon residues of concern in or on sorghum fodder and forage resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, WP, and EC formulation (each in separate tests) at 4 lb ai/A; ii) soil applications of a G formulation at 2 lb ai/A at planting or emergence (band); and iii) multiple foliar applications (by ground and in separate tests, aerial equipment), of a WP and EC formulation (each in separate tests) at 0.5 lb ai/A. Required tests must incorporate a 7-day PHI. Aerial applications must be made in a minimum of 1 gal water/A and ground applications must be made in a minimum of 5 gal water/A. Tests must be conducted in Texas, Kansas, Nebraska, and Missouri. The registrant must propose a maximum number of applications, or maximum seasonal use rate, for the label, and the required data must be produced using these maximums. Furthermore, tolerances must be proposed and/or appropriate data submitted for fodder and forage, since both are RACs of sorghum. Alternatively, the registrant may propose feeding and grazing restrictions.

85/ Residue data are required to determine diazinon residues of concern in or on wheat forage and straw after a single preplant broadcast application with the 50% WP formulation at 2 lb ai/A. This test must be conducted in Kansas. Alternatively, the registrant may request voluntary cancellation of SLN Registration No. KS-820017, which permits this use. Available data do indicate, however, that the SLN registrations of the 4 lb/gal EC and 14% G formulations will not result in residues exceeding the established 0.05 ppm tolerance for diazinon residues in or on wheat forage or straw.

86/ A tolerance of 60 ppm (not more than 40 ppm 24 hours after application) has been established for residues of diazinon per se in or on grass forage. A tolerance of 10 ppm has been established for residues in or on grass hay. However, additional data are required to fully support this group tolerance.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

Residue data are required to determine diazinon residues of concern in or on each of the representative commodities (Bermuda grass, brome grass or fescue, and bluegrass) treated, in separate tests, with all appropriate formulations under the maximum registered use and employing a 0-day PHI for grass. Data for grass hay should reflect presently registered minimum PHI's. Tests must be performed using ground and, in separate tests, aerial equipment. The registrant must propose a maximum seasonal foliar use rate for the label, and the required data must be produced using these maximums. Tests should be performed in California, Iowa, Michigan, Minnesota, Nebraska, New York, Pennsylvania, Washington, and Wisconsin.

Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications.

Residue data are required to determine diazinon residues in or on Bermuda grass, bluegrass, and brome grass (or fescue) treated at the maximum use rate and number of applications using the appropriate formulations registered under all of the SLN registrations for Florida, California, and Oregon, and employing a 0-day PHI for grass. Data for grass hay should incorporate presently registered minimum PHI's for each SLN registration. Applications should be made using ground/aerial equipment (separate tests) if appropriate. The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season, for the SLN labels for Florida and Oregon, the required data must be produced using these maximums, and revised labeling must be submitted that specifies the total number of applications and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. CA-800056, FL-790003, and OR-800062 which permit these uses.

Residue data are required to determine diazinon residues of concern in or on Oregon grown orchardgrass harvested at the usual time following broadcast applications of the 14% G during April at 3.5 lb ai/A. Application must be made by aerial and, in separate tests, ground equipment. Residue tests should be performed on grass and hay. The registrant must propose a maximum seasonal use rate, or a maximum number of applications per season for the label, and the required data must be produced using these maximums. Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications.

- 87/ Residue data are required to determine diazinon residues of concern in or on alfalfa treated with multiple foliar applications of the following formulations, and harvested in the following manner: i) an EC and WP (a separate test for each) at 0.5 lb ai/A, harvested as forage 0 days posttreatment; ii) an EC and WP at 1.5 lb ai/A, harvested as forage 2 days posttreatment; iii) a D formulation at 0.6 lb ai/A, harvested as forage 7 days posttreatment; iv) an EC, a D, and a WP (each in separate tests) at 0.5 lb ai/A, harvested as green hay 7 days

Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

post treatment and analyzed as field-cured hay (90% dry matter); and v) a D at 0.6 lb ai/A and an EC and a WP at 1.5 lb ai/A (a separate test for each), harvested as green hay 10 days post-treatment and analyzed as field-cured hay (90% dry matter). All treated test plots should have one preplant broadcast soil application of the G, EC, or WP formulation at 4 lb ai/A (a separate test performed for each formulation). The registrant must propose a maximum number of foliar applications per season for each use (hay and forage), or propose a maximum seasonal foliar use rate, for the label, and the required data must be produced using these maximums. Foliar application must be performed by aerial and in separate tests, ground equipment. Tests must be conducted in California, Idaho, Iowa, Kansas, Minnesota, Montana, Nebraska, New York, North Dakota, South Dakota, and Wisconsin.

88/ Residue data are required to determine diazinon residues of concern in or on birdsfoot trefoil harvested at a suitable post-treatment interval, to be proposed by the registrant, following a preplant broadcast soil incorporation with the 50% WP formulation at 8 lb ai/A. Tests should be conducted in Georgia, Kentucky, Missouri, New York, Ohio, Oklahoma, Pennsylvania, Tennessee, and Texas. If the registrant supports the use of diazinon on alfalfa, then he may request that all the other data required to support the use on birdsfoot trefoil be translated from the required data on alfalfa.

89/ Residue data are required to determine diazinon residues of concern in or on clover treated with multiple foliar applications of the following formulations, and harvested in the following manner: i) an EC and a WP (separate test for each) at 0.5 lb ai/A, harvested as forage 0 days posttreatment; ii) an EC and WP at 1.5 lb ai/A, harvested as forage 2 days posttreatment; iii) a D formulation at 0.6 lb ai/A, harvested as forage 7 days post-treatment; iv) an EC, a D, and a WP at 0.5 lb ai/A, harvested as green hay 7 days posttreatment (a separate test for each formulation) and analyzed as field-cured dried hay (90% dry matter); and v) a D at 0.6 lb ai/A and an EC and a WP at 1.5 lb ai/A (a separate test for each), harvested as green hay 10 days posttreatment and analyzed as field-cured hay (90% dry matter). All treated test plots should have one preplant broadcast soil application of the G, EC, or WP formulation at 4 lb ai/A (a separate test performed for each formulation). The registrant must propose a maximum number of foliar application per season for each use (hay and forage, low rate, and high rate), or propose a maximum seasonal foliar use rate, for the label, and the required data must be produced using these maximums. Foliar applications must be performed by both air and ground equipment (in separate tests). Tests must be conducted in Arkansas, Iowa, Kentucky, Missouri, New York, Oklahoma, Pennsylvania, Tennessee, Texas, and Virginia.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 90/ Residue data are required to determine diazinon residues of concern in or on lespedeza. The registrant must contact the Agency within the allowed ninety (90) day period for indicating intention to support this use, and either: a) request determination of the specific formulations, rates, and application schedule to be tested on lespedeza; or b) indicate support of the use of alfalfa and clover and request that the required data for those use patterns be used to support the use on lespedeza.
- 91/ Residue data are required to determine diazinon residues of concern in or on bananas receiving the following full-season application schedule: i) four soil applications (at 28-day intervals) of a G at 2 lb ai/A, using ground equipment; and ii) stem treatment with a G formulation at 1 g/stem. Tests must be conducted in Hawaii.

Residue data are also required to support SLN registrations. Residue data are required to determine diazinon residues of concern in or on bananas receiving the following full-season application schedule: multiple foliar applications of an EC and, in separate tests, a WP at 0.5 lb ai/A (applied by ground and air in separate tests). Tests must incorporate a 7-day PHI for foliar applications. The registrant must propose a maximum number of treatments, or use rate per season, for foliar treatments for the SLN labels, and the required data must be produced using these maximums. Tests must be conducted in Hawaii. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. HI-760003 and HI-760004 which permit these uses.

- 92/ Residues of concern must be determined in roasted beans and instant coffee produced from beans bearing measurable weathered residues. If residues concentrate in either of these processed products, appropriate food additive tolerances must be proposed.
- 93/ Residue data are required to determine diazinon residues of concern in or on cottonseed and cotton forage harvested 14 days after multiple foliar applications of a WP, an EC, and a D formulation (each in separate tests) at 1 lb ai/A, 1 lb ai/A, and 1.2 lb ai/A, respectively. All field trials must include ground and aerial application (in separate tests). The registrant must propose a maximum seasonal application rate or a maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California, Mississippi, and Texas.
- 94/ The registrant must submit data depicting diazinon residues of concern in soapstock processed from cottonseed bearing measurable weathered residues. If concentration is found to occur during processing, an appropriate tolerance must be proposed.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

95/ Residue data are required to determine diazinon residues of concern in or on figs, resulting from the following treatment schedule: multiple foliar applications, by aerial and ground equipment in separate tests, of a D formulation at 2.4 l ai/A, a WP at 2.8 lb ai/A by air and ground (in separate tests). Tests must incorporate a 5-day PHI when foliar use rates are not above 2.4 lb ai/A, and a 10-day PHI where use rates are higher. The registrant must propose a maximum seasonal application rate, or a maximum number of applications per season, for the label, and the required data must be produced using these maximums. Tests must be conducted in California.

Revised labeling must be submitted that specifies the total number of applications permitted per season and the interval between these applications.

Residue data are also required to support SLN registrations. Residue data are required to determine diazinon residues of concern in or on figs, resulting from the following treatment schedule: multiple soil drench applications of an EC formulation at 5 lb ai/A (in 130 gal water/A) at 14-day intervals. Tests must incorporate either a 0-day PHI for soil treatment, or an alternate PHI proposed by the registrant for this use. The registrant must propose a maximum seasonal application rate or a maximum number of applications per season for the SLN label, the required data must be produced using these maximums, and revised SLN labeling must be submitted which specifies the total number of applications permitted per season and the interval between these applications, as well as the PHI supported by the soil drench tests. Tests must be conducted in California. Alternatively, the registrant may request voluntary cancellation of SLN registration CA-830017 which permits this use.

96/ Data indicating whether diazinon residues of concern concentrate during drying of fresh figs bearing measurable weathered residues is required. If concentration occurs, an appropriate food additive tolerance for residues of concern in dried figs must be proposed.

97/ Residue data are required to determine residues of concern in or on hops harvested 14 days following the last of multiple foliar applications of a D formulation at 2 lb ai/A; and (in separate tests) a WP and an EC (each in separate tests) at 1 lb ai/A. Separate tests must be conducted using ground and aerial equipment. The registrant must propose a maximum seasonal application rate or a maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in Oregon and Washington.

98/ Residues must be determined in dried hops processed from hops bearing measurable residues. If residues are found to concentrate in dried hops, appropriate food/feed additive tolerances must be proposed for dried and spent hops.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 99/ Residue data are required to determine diazinon residues of concern in or on kiwifruit, resulting from multiple foliar (ground) applications of the 50% WP formulation at 0.5 lb ai/A. The registrant must propose a maximum seasonal application rate or a maximum number of applications per season for the label, and the required data must be produced using these maximums. Tests must be conducted in California and must reflect the established 1-year prefruit-set interval.
- 100/ Residue data are required to determine diazinon residues of concern in or on mushrooms grown in mushroom houses on which premise treatments have been made using a WP and (in separate tests) an EC at 1% concentrations in the finished spray. Studies must be conducted in Pennsylvania and California.
- Residue data are required to support the SLN registrations. Residue data are required to determine diazinon residues of concern in or on mushrooms following treatment of compost (prior to spawning) with a WP formulation at the maximum rate. Alternatively, the registrant may request voluntary cancellation of SLN Registration Nos. CA-800087, DE-790022, OR-800090, PA-790013, PA-810002, and PA-810007 which permit this use.
- 101/ Residue data are required to determine diazinon residues of concern in or on olives harvested after the following treatments: i) several multiple foliar applications of WP and EC formulations (each in separate tests) at 0.5 lb ai/100 gal; and the 40% WP (in separate tests) at 3.2 lb ai/A. Separate tests must be conducted using ground and aerial equipment; ii) multiple soil drench application of a 4 lb/gal EC at 5 lb ai/A. The registrant must propose a maximum seasonal application rate or a treatment numbers for foliar or soil treatments for the label, and the required data must be produced using these maximums. Tests must be conducted in California.
- 102/ No tolerance has been established or proposed for residues of diazinon in olive oil processed from diazinon-treated olives. Since submitted studies indicate that residue concentration occurs during processing of olives to produce oil, the registrant must submit an acceptable olive processing study and propose a food additive tolerance for residues in olive oil.
- 103/ Residue data are required to determine diazinon residues of concern in or on peanuts, peanut hulls, and peanut forage and hay, resulting from the following application schedule: i) four soil band applications of a G, a WP, and an EC (each in separate tests) at 2 lb ai/A; and ii) one broadcast or band (separate tests) soil application of a G at 43 lb ai/A, applied immediately prior to pegging. These tests must incorporate a 21-day PHI for nuts and hay, and a 7-day PHI for hulls and forage. Field trials must be conducted in Georgia, Texas, and North Carolina.



Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

- 104/ Residue data are required to determine diazinon residues of concern in meal, crude oil, refined oil, and soapstock derived from pea nuts bearing measurable weathered residues. If concentration of residues occurs during processing, the registrant must propose food/feed tolerances and submit appropriate residue data.
- 105/ Residue data are required to determine residues of concern in or on pineapples receiving the following full-season application schedule: i) multiple foliar applications of an EC and, in separate tests, a WP at 2 lb ai/A; ii) postharvest application(s) of a WP (and in separate tests) an EC formulation at 5 lb ai/500 gal/A; and iii) postharvest dip application of the 47.5% EC formulation at 2 lb ai/100 gal of water. Tests must be conducted using ground and aerial equipment. The registrant must propose a maximum seasonal use rate or application numbers for foliar and postharvest (vegetative slip) treatments for the label, and the required data must be produced using these maximums and must incorporate a 7-day PHI. Tests must be conducted in Hawaii.
- 106/ Residues must be determined in pineapple juice and bran processed from pineapples bearing measurable residues. If residues are found to concentrate in either of these processed products, an appropriate food/feed additive tolerance must be proposed.
- 107/ Residue data are required to determine diazinon residues of concern in or on sugarcane resulting from the following full-season application schedule: i) preplant broadcast soil application of a 10% G formulation at 3 lb ai/A; ii) four broadcast soil applications of a G formulation at 2.5 lb ai/A; iii) in-furrow soil (band) application of a G formulation at 6 lb ai/A, a WP at 4 lb ai/A and an EC at 4 lb ai/A (each in separate tests); and iv) multiple foliar applications of a WP and an EC (each in separate tests) at 0.5 lb ai/A. Separate tests must use ground and aerial equipment for foliar and soil broadcast applications. The registrant must propose a maximum seasonal use rate or maximum number of foliar applications per season for the label, and the required data must be produced using these maximums and must incorporate a 1-day PHI. Tests must be conducted in Florida, Hawaii, and Louisiana.
- 108/ Processing data for molasses, refined sugar, and bagasse, to determine the concentration of residues upon processing. These data must be generated from sugarcane bearing measurable weathered residues. If residues are found to concentrate in any of these commodities, appropriate food/feed additive tolerances must be proposed.
- 109/ All significant tobacco plant metabolites must be determine using ring-labeled [<sup>14</sup>C] diazinon. These compounds must be analyzed for the required residue studies listed below. Any significant translocated degradation products from soil and photodegradation products must also be determined.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

Data depicting residues of concern in or on tobacco resulting from the following full-season application schedule: i) preplant broadcast soil application of a G, a WP, an EC, and a D formulation (each in separate tests) at 3 lb ai/A; ii) at-plant or at-transplant soil application of a D formulation at 1.05 lb ai/A; iii) transplant water application of a WP and EC formulation (each in separate tests) at 0.5 lb ai/100/100 sq yd; and iv) multiple foliar applications of a WP and an EC formulation (each in separate tests) at 0.5 lb ai/A, and a D formulation at equipment. The tests should be conducted in North Carolina, Kentucky, Tennessee, and South Carolina. The registrant must propose a maximum seasonal use rate or maximum number of foliar and preplant broadcast soil applications per season for the label, and the required data must be produced using these maximums. Residue data are required for both green and cured tobacco, and for tobacco smoke. If total residues found in or on tobacco from the above-required studies are greater than 0.1 ppm, then: i) complete analytical methods must be submitted for detecting and quantifying diazinon and all metabolites of concern in or on tobacco and in tobacco smoke; and ii) pyrolysis products from diazinon must be characterized using ring-labeled [<sup>14</sup>C] diazinon.

110/ Residue data depicting diazinon residues of concern in or on watercress 5 days following the last of multiple foliar applications of an EC and a WP (in separate tests) at 0.5 lb ai/A. These tests must be performed in Hawaii. The registrant must propose a maximum seasonal foliar use rate or maximum number of foliar applications per season for the label, and the required data must be produced using these maximums.

Residue data are required to support the SLN registrations. Residue data depicting diazinon residues of concern in or on watercress 10 days following multiple foliar applications of a 50% WP formulation at 0.5 lb ai/A. The registrant must propose a maximum seasonal foliar use rate, or maximum number of applications per season, for the label, and the required data must be produced using these maximums. The tests must be done in Florida, California, and Hawaii. Revised SLN labeling must be submitted that specifies the total number of foliar applications permitted per season and the interval between these applications. Alternatively, the registrant may request voluntary cancellation of SLN registrations AL-820005, FL-820004, MD-820006, and PA-810025 which permeates of a 50% WP formulation on watercress at 0.5 lb ai/A with a 10-day PHI.

111/ Presently, the nature of the residue in ruminants (including milk) and in poultry (including eggs) is not adequately understood. Furthermore, additional residue data are required for the RACs and processed products comprising animal feeds. Therefore, the adequacy of the established tolerances cannot be assessed at this time. Upon fulfillment of the data requirements under Nature of the Residue in Animals, Storage Stability Data, and Magnitude of the Residue in Plants, the adequacy of the available data to support tolerances for residues in animal products will be evaluated.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

112/ No data have been submitted depicting residues of concern of diazinon in fish. If detectable residues of concern are found in water from the registered aquatic food crop uses, then residue studies on fish employing diazinon in water at levels which would be expected at the time of application are required.

113/ No data are available depicting the nature and magnitude of residues of diazinon in natural waters. The following data are required:

- Depiction of the nature of the residue and the level of residues of concern in the water of treated areas at regular intervals after application of a regimen of treatments represented a maximum use for watercress.

For watercress, multiple aerial and ground foliar applications at 10-day intervals of either an EC or a WP formulation must be made at 0.5 lb ai/A in 100 gal of spray suspension/A. Should detectable residues of concern occur in water then the registrant must either propose an ARLDW (Accepted Residue Level in Drinking Water) and a tolerance for residues from irrigation water in all crop groups, or propose restrictions in the registered uses for watercress so that water potentially to be used for irrigation or drinking is not exposed.

114/ No numerical tolerances have been established covering residues of diazinon in foods resulting from treatment of food-handling establishments. The available data are insufficient to evaluate the need for tolerances for residues resulting from these uses because: i) no studies were conducted depicting residues resulting from exaggerated exposure to diazinon by application of exaggerated rates, exposure of food in treated areas for longer periods than might be normally expected, and leaving food exposed in the immediate vicinity when diazinon applications are being made and ii) no tests were conducted depicting residues in or on foods resulting from the registered treatments with a pressurized liquid or a pressurized microencapsulated formulation. Therefore, the following additional data are required:

- Data depicting diazinon residues of concern in or on food resulting from applications of diazinon in a food service establishment and a food-manufacturing establishment or a food-processing establishment. Test at exaggerated rates are required for emulsifiable concentrates and dusts in these establishments and must be designed to incorporate the concerns raised in item (i) above. The registrant must submit a protocol within 90 days of receipt of this Registration Standard for this requirement. Tests are required in these establishments utilizing a pressurized liquid or a pressurized microencapsulated formulation applied in a 1% spray as a spot treatment covering 20% of the surface area (sprayed until completely wetted) of rooms of the establishment where food products are held, processed, and served. The registrant must determine, from the

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.240 Residue Chemistry Footnotes (cont'd)

above applications, residues of concern from direct deposition of spray droplets on food, volatilization, and subsequent absorption by foods, and all other possible modes of exposure of foods and residue transfer routes as outlined in the EPA Pesticide Assessment Guidelines, Subdivision O, Residue Chemistry, 171-4(C)(5). Representative food samples must be examined for residues of concern from these possible modes of exposure; the food must include an oily food (e.g., butter), baked cereal product, beverages, raw and processed meats, and fresh fruits and vegetables (lettuce). The registrant may propose a maximum use rate per unit floor area and apply the maximum lb ai in the required tests. Tests must also include conditions of possible misuse of diazinon and exaggerated exposure; e.g., applying an exaggerated rate or direct exposure of foods to the diazinon spray applied (refer to EPA Pesticide Guidelines for details of the type of data required).

If residues of concern are found to occur in or on foods from the registered food-handling establishment premise uses, then appropriate tolerances must be established.

115/ Study (ies) currently under review.

Table A  
Generic Data Requirements for Diazinon

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>2</sup> / Submission
<u>§158.290 Environmental Fate</u>						
<u>Degradation Studies - Lab</u>						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,E, F,G,H,I	Partially	00118021	Yes <sup>1</sup> /	9 Months
<u>Photodegradation</u>						
161-2 - In Water	TGAI or PAIRA	A,B,C,E, F,G,H	No		Yes <sup>10</sup> /	9 Months
161-3 - On Soil	TGAI or PAIRA	A,B,C,G, H	Yes	00153231,00153229	No	
161-4 - In Air	TGAI or PAIRA	A	No		Reserved <sup>2</sup> /	
<u>Metabolism Studies - Lab</u>						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,E,F, G,H	Yes	00118031,40028701	No	
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes	40028701	No	
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,G	Yes	40101501	No	
162-4 - Aerobic Aquatic	TGAI or PAIRA	C	No		Yes	27 Months

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.290 Environmental Fate</u>						
<u>Mobility Studies</u>						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A	Partially	00118034,40512601	Yes <sup>3,10/</sup>	9 Months
163-2 - Volatility (Lab)	TEP	A,E,F	No		Reserved <sup>4/</sup>	
163-3 - Volatility (Field)	TEP	A,E,F	No		Reserved <sup>5/</sup>	
<u>Dissipation Studies - Field</u>						
164-1 - Soil	TEP	A,B,H	No		Yes <sup>6/</sup>	27 Months progress report-6 months
164-2 - Aquatic (Sediment)	TEP	C	No		Yes	27 Months
164-3 - Forestry	TEP	G	No		Yes	27 Months
164-4 - Combination and Tank	TEP					
164-5 - Soil, Long-Term	TEP	A,B,H	No		No <sup>7/</sup>	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.290 Environmental Fate</u>						
<u>Accumulation Studies</u>						
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Reserved <sup>8/</sup>	
165-3 - Irrigated Crops	TEP	C	No		Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	A,B,C,G	No		Yes <sup>10/</sup>	12 Months
165-5 - In Aquatic Non- target Organisms	TEP	G	No		Reserved <sup>9/</sup>	
<u>Special Study</u>						
- small scale prospective ground water study	TEP	A,B,G	No		Reserved <sup>6/</sup>	

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.290 Environmental Fate Footnotes (cont'd)

- a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.
- 1/ Data are needed to characterize hydrolysis under sterile conditions.
  - 2/ Reserved pending receipt and evaluation of the required studies on laboratory volatility (§158.290 163-2), toxicology (§158.340), and reentry (§158.390).
  - 3/ Aged soil column leaching study, with complete identification of degradates, is required.
  - 4/ Reserved pending receipt and evaluation of the required studies on toxicology (§158.340) and reentry (§158.390).
  - 5/ Reserved pending receipt and evaluation of the required study on laboratory volatility (§158.290 163-2).
  - 6/ Field dissipation studies must include sampling to sufficient depths (i.e., where residues no longer persist), and a two (2) feet residue free zone (nondetectable residues) must be established below the deepest point of residue movement. Testing for the presence of diazinon, oxypyrimidine, and 2-(1-hydroxy 1-methyl)ethyl-4-6-hydroxypyrimidine is required at each sampling depth. The analytical method should be very sensitive, preferably at the 10 ppb level, to assess the extent of leaching. Interim results of these studies must be submitted 6 months after the studies are initiated for Agency assessment. A small-scale prospective ground water study under conditions where leaching is most likely to be observed is required if residues are detected moving beyond a 3 feet depth.
  - 7/ Based on the laboratory aerobic and anaerobic soil metabolism data, a long-term field dissipation study will not be needed.



Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.290 Environmental Fate Footnotes (cont'd)

- 8/ Reserved pending receipt and evaluation of the required confined rotational crop study (§158.290 165-1).
- 9/ Reserved pending receipt and evaluation of the required studies on laboratory fish accumulation (§158.290 165-4), aquatic dissipation (§158.290 164-2, and aquatic organisms (§158.145 72).
- 10/ Study (ies) currently under review.

Table A  
Generic Data Requirements for

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe for Submission
<u>Sec. 158.390 Reentry Protection</u>						
132-1 - Foliar Dissipation	TEP	A,B,C,E, F,G,H	Yes	40202901,40202902 40202903,40466601.	No	
132-2 - Soil Dissipation	TEP	A	No		No	
132-3 - Dermal Exposure	TEP	A,B,C,E, F,G,H.	No		No	
132-4 - Inhalation Exposure	TEP	A,B,C,E F,G,H.	No		No	
<u>Sec. 158.440 Spray Drift</u>						
201-1 - Droplet Size Spectrum	TEP	A,B,C,D,G	No		Yes <sup>1,2/</sup>	12 Months (3 months protocol)
202-1 - Drift Field Evaluation	TEP	A,B,C,D,G	No		Yes <sup>1,2/</sup>	12 Months (3 months protocol)

1/ The spray drift droplet spectrum and field evaluation may be done together in order to evaluate the drop spectrum that are associated with actual field use patterns.

2/ A protocol must be submitted before attempting these studies. An acceptable protocol must be submitted within ninety (90) days of receipt of this Registration Standard.

Table A  
Generic Data Requirements for Diazinon

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a</sup> / Submission
<u>§158.340 Toxicology</u>						
81-1 - Acute Oral - Rat	TGAI	All	Yes	00146179	No	
81-2 - Acute Dermal	TGAI	All	Yes	00146180	No	
81-3 - Acute Inhalation	TGAI	All	Yes	00109043	No	
81-7 - Acute Delayed Neurotoxicity	TGAI	All	No		Yes <sup>1,12</sup> /	12 Months
<u>Subchronic Testing</u>						
82-1 - 90-Day Feeding						
- Rodent	TGAI	All	No		Yes <sup>2,12</sup> /	15 Months
- Nonrodent	TGAI	All	No		Yes <sup>2,12</sup> /	18 Months
82-2 - 21-Day Dermal	TGAI	All <sup>3</sup> /	No		Yes <sup>2,12</sup> /	12 Months
82-3 - 90-Day Dermal	TGAI	All <sup>3</sup> /	No		Reserved <sup>4</sup> /	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.340 Toxicology</u>						
<u>Subchronic Testing (cont'd)</u>						
82-4 - <u>21-Day</u> or 90-Day Inhalation	TGAI	All <sup>5/</sup>	No		Yes <sup>2,12/</sup>	15 Months
82-5 - 90-Day Neurotoxicity	TGAI	All	No		Reserved <sup>6/</sup>	
<u>Chronic Testing</u>						
83-1 - Chronic Testing						
- Rodent	TGAI	A,C,E	No		Yes <sup>2,7/</sup>	50 Months
- Nonrodent	TGAI	A,C,E	No		Yes <sup>2,7/</sup>	50 Months
83-2 - Oncogenicity						
- Rat	TGAI	A,C,E	Yes	00073372	No	
- Mouse	TGAI	A,C,E	Yes	00073372	No	
83-3 - Teratogenicity						
- Rat	TGAI	All	Yes	00153017	No	
- Rabbit	TGAI	All	Yes	00079016,00079017	No	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.340 Toxicology</u>						
<u>Chronic Testing (cont'd)</u>						
83-4 - Reproduction	TGAI	A,C,E	No		Yes	39 Months (90 Days Protocol)
<u>Mutagenicity Testing</u>						
84-2 - Gene Mutation	TGAI	All	Partially	00132952	Reserved <sup>8,12/</sup>	
84-2 - Chromosome Aberration	TGAI	All	No	--	Yes <sup>9,12/</sup>	12 Months
84-4 - Other Mechanisms of Mutagenicity (Sister Chromatid Exchange)	TGAI	All	Partially	00142045	Yes <sup>10,12/</sup>	12 Months
<u>Special Testing</u>						
85-1 - General Metabolism	PAI or PAIRA	A,C,E	No		Yes	24 Months
- Antidote			No		Reserved <sup>11,12/</sup>	

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.340 Toxicology Footnotes:

- a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.
- 1/ The Agency recently reviewed an acute neurotoxicity study in hens which was found to be "equivocal." This study is unacceptable.
  - 2/ Studies conducted must establish NOEL's for plasma, RBC, and brain cholinesterase activity as well as standard parameters recommended in Subdivision F of the EPA Health Assessment Guidelines.
  - 3/ All uses resulting in repeated dermal exposure.
  - 4/ Reserved pending results of the 21-day dermal study.
  - 5/ All uses resulting in repeated indoor inhalation exposure.
  - 6/ Reserved pending results of the acute delayed neurotoxicity study (81-7).
  - 7/ Registrants who conduct chronic feeding and/or oncogenicity studies should inform the Agency in writing of the dosage levels planned and their reasons for believing that the highest dose approaches or equals the maximum tolerated dose observed in subchronic or range-finding studies, and must also consult with the Agency to determine that the appropriate dosage levels are being used in the chronic feeding and/or oncogenicity studies. If EPA subsequently determines that the study was conducted using a dosage rate that was too low to assess long-term effects, the study may be deemed not to satisfy the data requirement.
  - 8/ The Agency will assess the need for in vitro mammalian gene mutation studies (i.e., mouse lymphoma L51784 and Chinese hamster type assays) after evaluating data required to address potential for structural chromosomal aberrations and potential for inducing sister chromatid exchange both in vivo and in vitro.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.340 Toxicology Footnotes:

- 9/ A mouse micronucleus test is required to evaluate structural chromosome aberrations.
- 10/ Studies on both in vivo and in vitro sister chromatid exchange assays are required. In addition, registrants must submit a summary table of all readily available mutagenicity studies on diazinon including literature references.
- 11/ The Agency is reserving judgment on the need for this study. In response to the 1987 DCI, the registrant has committed to submit a published literature summary of reasonable scope demonstrating the effectiveness of the antidotes, atropine, and 2-PAM, in lieu of conducting effectiveness studies. After review of the submission, the Agency will determine if any additional studies are required to adequately define the effectiveness of atropine and 2-PAM as antidotes for diazinon.
- 12/ Study(ies) currently under review.

Table A  
Generic Data Requirements for Diazinon

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a</sup> / Submission
<u>§158.490 - Wildlife and Aquatic Organisms</u>						
<u>Avian and Mammalian Testing</u>						
71-1 - Avian Acute Oral Toxicity						
Waterfowl	TGAI	A,B,C,E, I,H	Yes	40922901,40922902	No	
	EP	A,B,C,E, I,H	No		Yes <sup>1</sup> /	9 Months
- Songbird	TGAI	A,B,C,E, I,H	Yes	00020560	No	
	EP	A,B,C,E, I,H	Partially	00148695	Yes <sup>2</sup> /	9 Months (90 Days) Protocol)
- Upland game bird	TGAI	A,B,C,E, I,H	Yes	00148703	No	
	EP	A,B,C,E, I,H	Yes	00148703	No	
71-2 - Avian Dietary LC <sub>50</sub>						
- Waterfowl	TGAI	A,B,C,E, I,H	Partially	00022923	Yes	9 Months
	EP	A,B,C,E, I,H	Partially	40910901	Yes <sup>3</sup> /	9 Months



Table A  
Generic Data Requirements for Diazinon (cont'd)

<u>Data Requirement</u>	<u>Composition</u>	<u>Use Patterns</u>	<u>Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)</u>	<u>Bibliographic Citation</u>	<u>Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?</u>	<u>Timeframe For Data Submission</u>
<u>\$158.490 - Wildlife and Aquatic Organisms</u>						
<u>Avian and Mammalian Testing (cont'd)</u>						
71-2 - Avian Dietary LC <sub>50</sub> (cont'd)						
- Songbird	TGAI	A,B,C,E, I,H	No		No	
	EP	A,B,C,E, I,H	No		Yes <sup>4/</sup>	9 Months (90 Days Protocol)
- Upland game bird	TGAI	A,B,C,E, I,H	Yes	00022923	No	
	EP	A,B,C,E, I,H	Yes	40910905,40910902	No	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.490 - Wildlife and Aquatic Organisms</u>						
<u>Avian and Mammalian Testing (cont'd)</u>						
71-4 - Avian Reproduction						
- Upland Game Bird	TGAI	A,B,C,H	No		Yes <sup>5/</sup>	24 Months (90 Days Protocol)
- Waterfowl	TGAI	A,B,C,H	No		Yes <sup>6/</sup>	24 Months (90 Days Protocol)
71-5 - Actual Field Testing For Birds	EP	A,B,C,H	No		Yes <sup>7/</sup>	30 Months (90 Days Protocol)

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>\$158.490 - Wildlife and Aquatic Organisms</u>						
<u>Aquatic Organism Testing</u>						
72-1 - Freshwater Fish LC <sub>50</sub>						
- Coldwater	TGAI	A,B,C, E,I,H	Yes	00104923,40094602	No	
	EP	A,B,C, E,I,H	Partially	00118393	Yes <sup>8,18/</sup>	9 Months
- Warmwater	TGAI	A,B,C, E,I,H	Yes	00104923,40094602, 40910904.	No	
	EP	A,B,C, E,I,H	Partially	00118393	Yes <sup>9,18/</sup>	9 Months
72-2 - Freshwater Invertebrate LC <sub>50</sub>						
	TGAI	A,B,C, E,I,H	Yes	00109022,40094602	No	
	EP	A,B,C, E,I,H	Partially	00121283	Yes <sup>10/</sup>	9 Months
72-3 - Estuarine and Marine Organisms LC <sub>50</sub>						
- Fish	TGAI	A,B,C	Yes	40914801	No	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.490 - Wildlife and Aquatic Organisms</u>						
<u>Aquatic Organism Testing (cont'd)</u>						
72-3 - Estuarine and Marine Organisms LC <sub>50</sub> (cont'd)						
- Mollusk	TGAI	A,B,C	No		Yes <sup>11,18/</sup>	12 Months
	EP	A,B,C	No		Reserved <sup>12/</sup>	
- Shrimp	TGAI	A,B,C	No		Yes <sup>13,18/</sup>	12 Months
	EP	A,B,C	No		Reserved <sup>14/</sup>	
72-4 - Fish Early Life Stage and Invertebrate Life Cycle						
- Freshwater						
- Fish	TGAI	A,B,C,H	No		Yes <sup>14,18/</sup>	15 Months
- Invertebrates	TGAI	A,B,C,H	No		Yes <sup>14,18/</sup>	15 Months
72-5 - Fish Life Cycle	TGAI	A,B,C,H	No		Reserved <sup>15/</sup>	
72-6 - Aquatic Organisms Accumulation	PAIRA	A,B,C,H	No		Yes <sup>16,18/</sup>	12 Months

**Table A**  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Pattern	Does EPA Have Data to Satisfy This Requirement? (Yes, No, or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA 3(c)(2)(B)	Timeframe For Data Submission
<u>§158.490 - Wildlife and Aquatic Organisms</u>						
<u>Aquatic Organism Testing (cont'd)</u>						
72-7 - Simulated or Actual Field Testing						
- Aquatic Residue Monitoring	EP	A,B,C,H	No		Yes <sup>17/</sup>	30 Months (90 Days (Protocol)

a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.

<sup>17/</sup> Avian acute oral toxicity (single-dose oral LD<sub>50</sub>) testing with a waterfowl species (preferably the mallard) is required with diazinon 14% (ai) granular formulation and with the 48% (ai) emulsifiable concentrate formulation. For testing granular formulations, the LD<sub>50</sub> is to be calculated as the number of granules required to cause 50% mortality. Additional testing with on other end-use product formulations are reserved pending results of these studies.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.490 Wildlife and Aquatic Organism Footnotes (cont'd)

- 2/ Avian acute oral toxicity (single-dose oral LD<sub>50</sub>) testing with a songbird species (preferably the brown-headed cowbird) is required with diazinon 14% (ai) granular formulation and with the 48% (ai) emulsifiable concentrate formulation. For testing granular formulations, the LD<sub>50</sub> is to be calculated as the number of granules required to cause 50% mortality. The protocol must be submitted within ninety (90) days of receipt of this standard for Agency approval before conducting this study. Additional testing on other end-use product formulations is reserved pending results of these studies.
- 3/ Avian subacute dietary toxicity (dietary LC<sub>50</sub>) testing with a waterfowl species (preferably mallard) is required with diazinon 48% (ai) emulsifiable concentrate formulation. Additional testing on other end-use product formulations are reserved pending results of these studies.
- 4/ Avian subacute dietary toxicity (dietary LC<sub>50</sub>) testing with a songbird species (preferably the brown-headed cowbird) is required with diazinon 48% (ai) emulsifiable concentrate formulation. Additional testing with on other end-use product formulations are reserved pending results of these studies. The protocol must be submitted with ninety (90) days of receipt of this Standard for Agency approval before conducting this study.
- 5/ Avian reproduction studies with TGAI are required for an upland game bird species (preferably the bobwhite or other native quail or the ringed-neck pheasant). The TGAI to be tested must be identified with respect to purity. The percent (or parts per million) content of all organophosphorus impurities must be identified. In particular, the concentration of sulfotepp, if any, must be stated. In addition, plasma cholinesterase levels must be measured. An acceptable protocol must be submitted.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.490 Wildlife and Aquatic Organism Footnotes (cont'd)

- 6/ Avian reproduction studies with TGAI are required for a waterfowl species (preferably the mallard). The TGAI to be tested must be identified with respect to purity. The percent (or parts per million) content of all organophosphorus impurities must be identified. In particular, the concentration of sulfotep, if any, must be stated. The standard protocol, as in the EPA Guidelines, should be expanded to include behavioral monitoring for such effects as decreased nest attentiveness (i.e., birds must be allowed to naturally incubate eggs). In addition, plasma cholinesterase levels must be measured. An acceptable protocol must be submitted to the Agency for approval a minimum of 90 days prior to the anticipated date of test initiation.
- 7/ Actual field testing with birds is required as per 40 CFR 158.490. Testing conducted on alfalfa and apples must be done with the 48% ai diazinon emulsifiable concentrate at the maximum application rate (4 lb ai/A). Testing conducted on corn with the 14.3% ai granular must be conducted in no-till fields to ensure the greatest likelihood of wildlife exposure. Testing must include a minimum of 8 sites plus a control in each geographic area. Two geographic areas must be studied for each of the following crops: alfalfa, corn, and apples. Areas selected should attempt to maximize the variety of avian exposure and improve the chances that potential adverse effects will not be missed. Residue analysis of avian food items, and carcass searching to determine the extent of diazinon-induced mortality is required. Additional field testing, including testing on other crops, is reserved pending results of these studies. Cancellation of any of the above use patterns would obviate the need for testing of these uses. However, since further studies are reserved pending the results of the above testing, other sites may be required to be substituted. Acceptable protocols for conducting the studies, including quantitative description of the proposed test sites and detailed descriptions of proposed methodology and sample sizes, must be submitted to the Agency no later than 90 days prior to the anticipated date of study initiation. In developing protocols, the registrant must follow the Agency's most recent draft "Guidance Document for Conducting Terrestrial Field Studies", for level I studies.

Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.490 Wildlife and Aquatic Organism Footnotes (cont'd)

- 8/ Acute toxicity (LC<sub>50</sub>) studies with a warmwater fish species are required using a diazinon 48% ai emulsifiable concentrate EP.
- 9/ Acute toxicity (LC<sub>50</sub>) studies with a coldwater fish species are required using a 48% ai diazinon emulsifiable concentrate EP.
- 10/ Acute toxicity (LC<sub>50</sub>) studies with a freshwater invertebrate species are required with a 48% ai diazinon emulsifiable concentrate EP.
- 11/ Acute toxicity testing of the TGAI to oysters is required because diazinon is labeled for use on crops grown in more than 300,000 acres in coastal counties and other crops/sites with a large percentage of of their acreage in coastal areas. These include citrus, cotton, corn, cranberries, clover, peanuts, pasture, sorghum, sugarcane, and tobacco. The TGAI to be tested must be identified with respect to purity. The percent (or parts per million) content of all organophosphorus impurities must be identified. In particular, the concentration of sulfotepp, if any, must be stated.
- 12/ Formulated product testing for acute toxicity to estuarine and marine organisms is reserved pending the results of testing with TGAI.
- 13/ Acute toxicity testing of the TGAI to shrimp is required because diazinon is labeled for use on crops grown in more than 300,000 acres in coastal counties and other crops/sites with a large percentage of their acreage in coastal areas. These include citrus, cotton, corn, cranberries, clover, peanuts, pasture, sorghum, sugarcane, and tobacco. The TGAI to be tested must be identified with respect to purity. The percent (or parts per million) content of all organophosphorus impurities must be identified. In particular, the concentration of sulfotepp, if any, must be stated.
- 14/ The TGAI to be tested in both the fish early life stage and aquatic invertebrate life cycle studies must be identified with respect to purity. The percent (or parts per million) content of all organophosphorus impurities must be identified. In particular, the concentration of sulfotepp, if any, must be stated.



Table A  
Generic Data Requirements for Diazinon (cont'd)

§158.490 Wildlife and Aquatic Organism Footnotes (cont'd)

15/ Reserved pending the results of the fish early life stage testing, §158.490 72-4, and aquatic residue monitoring.

16/ Testing is required as per §158.490 (72-6) and §158.490 (165-4), laboratory fish accumulation. Testing with additional species are reserved, pending receipt and review of this data.

17/ Aquatic residue monitoring is required on alfalfa, apples, citrus, and cranberries. A variety of aquatic habitats must be sampled whenever possible (e.g., shallow ponds, deeper ponds, streams, bays, etc.) Maximum application rates should be tested (eg., 10 lb ai/A for citrus). Citrus groves must be flooded to maximize potential aquatic exposure. Additional residue monitoring studies are reserved pending results of these studies.

Full field testing to examine effects on aquatic invertebrates and fish is required on alfalfa, apples, citrus, and cranberries. A minimum of three sites per test is required. The study duration is a minimum of two (2) years.

Mesocosm studies are an alternative to full field testing, however; mesocosm studies must be conducted on a range of test levels that are adequate to model the full range of potential aquatic exposure under diazinon's use patterns. Additional field testing on other sites is reserved pending results of these studies. Voluntary cancellation of any of the above uses, including both FIFRA section 3 and section 24c registrations, would obviate the need for testing of those uses. However, since further studies are pending the results of the above testing, other sites may be required to be substituted. Acceptable protocols for conducting the studies, including quantitative description of the proposed test sites and detailed descriptions of proposed methodology and sample sizes, must be submitted to the Agency no later than 90 days prior to the anticipated date of study initiation. A draft Guidance Document regarding mesocosm studies is presently available. A final document will be developed following an anticipated Scientific Advisory Panel review later this year.

18/ Study (ies) currently under review.

Table A  
Generic Data Requirements for Diazinon

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a</sup> / Submission
<u>\$158.540 Plant Protection</u>						
<u>TARGET AREA PHYTOTOXICITY</u>						
121-1 - Target Area Phytotoxicity	TEP	B	No		No	
<u>NONTARGET AREA PHYTOTOXICITY</u>						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B	Yes	40509805	No	
122-1 - Vegetative Vigor	TGAI	B	Yes	40509804	No	
122-2 - Aquatic Plant Growth	TGAI	B	Yes	40509806	No	
TIER II						
122-1 - Seed Germination/ Seedling Emergence	TGAI	B	No		Yes <sup>1</sup> /	9 Months
122-1 - Vegetative Vigor	TGAI	B	No		Yes <sup>1</sup> /	9 Months
122-2 - Aquatic Plant Growth	TGAI	B	Yes	40509806	No	

Table A  
Generic Data Requirements for Diazinon (cont'd)

<u>Data Requirement</u>	<u>Composition</u>	<u>Use Patterns</u>	<u>Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)</u>	<u>Bibliographic Citation</u>	<u>Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?</u>	<u>Timeframe For Data Submission</u>
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¶158.540 Plant Protection

NONTARGET AREA PHYTOTOXICITY (Cont'd)

TIER III

124-1 - Terrestrial Field	TGAI	B	No		Reserved <sup>2/</sup>	
124-2 - Aquatic Field	TGAI	B	No		Reserved <sup>2/</sup>	

a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.

<sup>1/</sup> Study (ies) currently under review.

<sup>2/</sup> Reserved pending results of Tier II.

Table A  
Generic Data Requirements for Diazinon

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a/</sup> Submission
<u>158.590 Nontarget Insects</u>						
<u>NONTARGET INSECT TESTING - POLLINATORS</u>						
141-1 - Honey Bee Acute Contact LD <sub>50</sub>	TGAI	A,B,G,H	Yes	00036935,00162751	No	
141-2 - Honey Bee - Toxicity Residues on Foliage	EP	A,B,G,H	No		No	
141-4 - Honey Bee Subacute Feeding Study	Reserved <sup>1/</sup>					
141-5 - Field Testing for Pollinators	EP	A,B,G,H	No		No <sup>2/</sup>	
<u>NONTARGET INSECT TESTING - AQUATIC INSECTS</u>						
142-1 - Acute Toxicity to Aquatic Insects	EP				Reserved <sup>3/</sup>	
142-2 - Aquatic Insect Life Cycle Study	EP				Reserved <sup>3/</sup>	
142-3 - Simulated or Actual Field Testing for Aquatic Insects	EP				Reserved <sup>3/</sup>	

Table A  
Generic Data Requirements for Diazinon (cont'd)

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>158.590 Nontarget Insects</u>						
<u>NONTARGET INSECT TESTING - PREDATORS AND PARASITES</u>						
143-1 thru 143-3	EP	A,B,G,H	N/A	05003978,05004148 4/ 05005640,05009345.	Reserved4/	

a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.

1/ This requirement is reserved pending development of test methodology.

2/ Data reviewed in lower-tier studies do not indicate the need for field testing.

3/ This requirement is reserved pending Agency decision as to whether the data requirement should be established.

4/ These studies were reviewed in order to provide an assessment of diazinon to non-target insects. Since the Agency has not determined whether this data requirement should be established, an evaluation of these studies to determine fulfillment of the data requirement is not appropriate at this time.

Table B  
Product-Specific Data Requirements for Manufacturing-Use Products Containing Diazinon

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a</sup> / Submission
<u>Part 158, Subpart C, Product Chemistry</u>					
<u>Product Identity and Composition</u>					
61-1 - Product Identity and	MP	No <sup>1</sup> /		Yes <sup>2</sup> /	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No <sup>1</sup> /		Yes <sup>3</sup> /	9 Months
61-3 - Discussion of Formation of Impurities	MP	No <sup>1</sup> /		Yes <sup>4</sup> /	9 Months
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis of Product Samples	MP	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
62-2 - Certification of Ingredient Limits	MP	No <sup>1</sup> /		Yes <sup>6</sup> /	9 Months
62-3 - Analytical Methods to Verify Certified Limits	MP	No <sup>1</sup> /		Yes <sup>7</sup> /	9 Months
<u>Physical and Chemical Characteristics</u>					
63-2 - Color	MP	No <sup>1</sup> /		Yes <sup>8</sup> /	9 Months

Table B  
Product-Specific Data Requirements for Manufacturing-Use Products Containing Diazinon (cont'd)

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>Part 158, Subpart C, Product Chemistry</u>					
<u>Physical and Chemical Characteristics (cont'd)</u>					
63-3 - Physical State	MP	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
63-4 - Odor	MP	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
63-7 - Density, Bulk Density, or Specific Gravity	MP	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
63-12 - pH	MP	No <sup>1</sup> /		Yes <sup>5,9</sup> /	9 Months
63-14 - Oxidizing or Reducing Agent	MP	No <sup>1</sup> /		Yes <sup>8,10</sup> /	9 Months
63-15 - Flammability	MP	No <sup>1</sup> /		Yes <sup>8,11</sup> /	9 Months
63-17 - Storage Stability	MP	No <sup>1</sup> /		Yes <sup>8,12</sup> /	9 Months
63-18 - Viscosity	MP	No <sup>1</sup> /		Yes <sup>8,14</sup> /	9 Months
63-19 - Miscibility	MP	No <sup>1</sup> /		Yes <sup>8,13</sup> /	9 Months
63-20 - Corrosion Characteristics	MP	No <sup>1</sup> /		Yes <sup>8</sup> /	15 Months
<u>Other Requirements</u>					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

Table B  
Product-Specific Data Requirements for Manufacturing-Use Products Containing Diazinon (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes

- a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.
- 1/ Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.
- 2/ The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient in each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned code numbers.
- 3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.
- 4/ A detailed discussion of all impurities that are or may be present at  $\geq 0.1\%$ , based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. The discussion must specifically address the potential for the formation of diazoxon, TEPP and its sulfur derivatives.
- 5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.



Table B  
Product-Specific Data Requirements for Manufacturing-Use Products Containing Diazinon (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes (cont'd)

- 6/ Upper and lower limits for the active ingredients and each intentionally added inert, and upper limits for each impurity present at  $\geq 0.1\%$  (w/w) and each "toxicologically significant" impurity present at  $< 0.1\%$  (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimates based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certification must be submitted on EPA Form 857 Rev. 2-85.
- 7/ Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.
- 8/ Physicochemical characteristics (color, physical state, odor, melting point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, must be submitted.
- 9/ Data required if the test substance is dispersible in water.
- 10/ Data required if the product contains an oxidizing or reducing agents.
- 11/ Data required if the product contains combustible liquids.
- 12/ The test must be conducted with the product in its commercial package. Diazinon and its sulfur derivatives must be analyzed for at the beginning and at the end of the test period. Products must be tested for one year under either of the following conditions: (i) at 20°C or 25°C, and, if the package is permeable, at a relative humidity of 50%; (ii) under warehouse conditions which reflect the expected storage conditions of the commercial product.
- 13/ Data required if the product is a liquid.
- 14/ Data required if the product is a liquid and is to be diluted with petroleum solvents.

Table B  
Product-Specific Data Requirements for Manufacturing Use Products Containing Diazinon

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a</sup> / Submission
<u>§158.340 Toxicology</u>						
81-1 - Acute Oral - Rat	MUP	All	No		Yes <sup>1,3</sup> /	9 Months
81-2 - Acute Dermal	MUP	All	No		Yes <sup>1</sup> /	9 Months
81-3 - Acute Inhalation	MUP	All	No		Yes <sup>1</sup> /	9 Months
81-4 - Eye Irritation	MUP	All	No		Yes <sup>1</sup> /	9 Months
81-5 - Dermal Irritation	MUP	All	No		Yes <sup>1</sup> /	9 Months
81-6 - Dermal Sensitization	MUP	All	No		Yes <sup>1</sup> /	9 Months
<u>Special Testing</u>						
6-Week Oral Feeding (Rat)	MUP	All	No		Yes <sup>1,2,3</sup> /	15 Months (90 day protocol)

Table B  
Product-Specific Data Requirements for Manufacturing Use Products Containing Diazinon

Part 158.340 Toxicology Footnotes

- a/ For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.
- 1/ Each registrant of a manufacturing use product must submit product specific data for his own product.
- 2/ This study must define NOELs for plasma, erythrocyte and brain Cholinesterase inhibition.
- 3/ In order to determine the similarity or dissimilarity between the registered manufacturing use products, the Agency requires that the Sprague-Dawley strain of rat be used for this study. Registrants are required to contact the Agency prior to initiation of this study for the purpose of establishing standard experimental procedures for required testing.

Table C  
Product-Specific Data Requirements for End-Use Products  
Containing Diazinon

<u>Data Requirement</u>	<u>Composition</u>	<u>Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)</u>	<u>Bibliographic Citation</u>	<u>Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?</u>	<u>Timeframe For Data<sup>a</sup>/ Submission</u>
<u>Part 158, Subpart C, Product Chemistry</u>					
<u>Product Identity and Composition</u>					
61-1 - Product Identity and Composition	EP	No <sup>1</sup> /		Yes <sup>2</sup> /	9 Months
61-2 - Description of Beginning Materials and Manufacturing Process	EP	No <sup>1</sup> /		Yes <sup>3</sup> /	9 Months
61-3 - Discussion of Formation of Impurities	EP	No <sup>1</sup> /		Yes <sup>4</sup> /	9 Months
<u>Analysis and Certification of Product Ingredients</u>					
62-1 - Preliminary Analysis of Product Samples	EP	No <sup>1</sup> /		Yes <sup>5</sup> /	9 Months
62-2 - Certification of Ingredient Limits	EP	No <sup>1</sup> /		Yes <sup>6</sup> /	9 Months
<u>Physical and Chemical Characteristics</u>					
63-7 - Density, Bulk Density, or Specific Gravity	EP	No <sup>1</sup> /		Yes <sup>7</sup> /	9 Months

Table C  
Product-Specific Data Requirements for End-Use Products  
Containing Diazinon

Data Requirement	Composition	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data <sup>a/</sup> Submission
<u>Part 158, Subpart C, Product Chemistry</u>					
<u>Physical and Chemical Characteristics (cont'd)</u>					
63-12 - pH	EP	No <sup>1/</sup>	Yes <sup>7,8/</sup>		9 Months
63-15 - Flammability	EP	No <sup>1/</sup>	Yes <sup>7,9/</sup>		9 Months
<u>Other Requirements</u>					
Special Storage Stability	EC	No	Yes <sup>10/</sup>		27 Months

<sup>a/</sup> For those data requirements identified in the May 1987 Comprehensive Data Call-In, the operative due dates are those stipulated in that document or as officially extended by the EPA in response to registrant's request. For any new data requirement imposed by this Registration Standard, the operative due dates are those imposed under this Registration Standard.

- 1/ Although product chemistry may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New data requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.
- 2/ The chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, and purpose of the active ingredient in each intentionally added inert must be provided. For the active ingredients, the following must also be provided: the product, common and trade names; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned code numbers.

Table C  
Product-Specific Data Requirements for End-Use Products  
Containing Diazinon (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes (cont'd)

reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/ A detailed discussion of all impurities that are or may be present at  $\geq 0.1\%$ , based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted. The discussion must specifically address the formation of diazoxon, TEPP and its sulfur derivatives.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used. Required for products produced by an integrated system.

6/ Upper and lower limits for the active ingredients and each intentionally added inert, and upper limits for each impurity present at  $\geq 0.1\%$  (w/w) and each "toxicologically significant" impurity present at  $< 0.1\%$  (w/w) must be provided and certified. Also, an explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimates based on amounts of ingredients used, etc.). Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. Certification must be submitted on EPA Form 857 Rev. 2-85.

7/ Density (or specific gravity, pH, and flammability information must be submitted for each product as part of the Confidential Statement of Formula. Other Physicochemical characteristics (color, physical state, odor, melting point, solubility, vapor pressure, dissociation constant, partition coefficient, and stability) as required in 40 CFR 158.190 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, are not required at this time.

8/ Data required if the test substance is dispersible in water.

9/ Data required if the product contains combustible liquids.

Table C  
Product-Specific Data Requirements for End-Use Products  
Containing Diazinon (cont'd)

Part 158, Subpart C, Product Chemistry Footnotes (cont'd)

10/ The test must be conducted for each EC (emulsifiable concentrate) product in its commercial package. Five representative samples must be analyzed. Diazinon and any of its impurities and/or degradates must be identified and quantitated at the beginning and at the end of the test period. All compounds occurring at  $\geq 0.1\%$  in the product must be identified and quantitated. Compounds of special toxicological concern such as diazoxon, TEPP and its sulfur derivatives will require characterization and/or analysis regardless of the concentration at which they are present.

Packaging must be open prior to analysis at each of the required sample analysis testing intervals; immediately after batch processing, 6 months, 15 months, 18 months and 24 months. Products must be stored under typical conditions which reflect the expected storage conditions of the product.

Table C  
Product Specific Data Requirements for End-Use Products  
Containing Diazinon

Data Requirement	Composition	Use Patterns	Does EPA Have Data to Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
<u>§158.340 Toxicology</u>						
81-1 - Acute Oral - Rat	TEP 1/	All	No		Yes	9 Months
81-2 - Acute Dermal	TEP 1/	All	No		Yes	9 Months
81-3 - Acute Inhalation	TEP 1/	All	No		Yes	9 Months
81-4 - Eye Irritation	TEP 1/	All	No		Yes	9 Months
81-5 - Dermal Irritation	TEP 1/	All	No		Yes	9 Months
81-6 - Dermal Sensitization	TEP 1/	All	No		Yes	9 Months
<u>Special Testing</u>						
81-1 - Acute Oral - Rat	EP	All	No		Reserved 2/	
81-2 - Acute Dermal	EP	All	No		Reserved 2/	



Table C  
Product Specific Data Requirements for End-Use Products  
Containing Diazinon

§ 158.340 Toxicology Footnotes

1/ Testing is required on a typical end-use formulation containing the following active ingredient percentages:

<u>FORMULATION</u>	<u>DIAZINON</u>	<u>PETROLEUM DISTILLATE</u>	<u>XYLENE</u>
Emulsifiable concentrate	48%	(25-40)	
	48%		(25-40)
	25%	(50-60)	
	25%		(50-60)
	12.5%	(30-40)	
	12.5%	(50-60)	
	12.5%		(50-60)
Dust	1.0%	N.A.	N.A.
Wettable Powder	50%	N.A.	N.A.
Granular	14%	N.A.	N.A.
Granular	5.0%	N.A.	N.A.

2/ Testing is reserved pending evaluation of Table C product chemistry data requirements.

## II. LABELING APPENDICES

## SUMMARY-1

### LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

## SUMMARY-2

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

<u>Size of Label on Front Panel in Square Inches</u>	<u>Signal Word Minimum Type Size All Capitals</u>	<u>"Keep Out of Reach of Children" Minimum Type Size</u>
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.  
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.  
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.  
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

### SUMMARY-3

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY  
Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

#### SUMMARY-4

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

#### Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

- a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv)).
- b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

- a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

#### SUMMARY-5

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

## SUMMARY-6

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

### COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.



## SUMMARY-7

## LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	<u>PLACEMENT ON LABEL</u>		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & cross-bones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

## LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

## PHYSICAL-CHEMICAL HAZARDS

<u>Criteria</u>	<u>Required Label Statement</u>
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. <u>ALL OTHER PRESSURIZED CONTAINERS</u>	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STORAGE INSTRUCTIONS FOR PESTICIDESHeading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."
2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

"Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."
3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."
4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."
5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

<u>Container Type</u>	<u>Statement</u>
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). <u>Rinse thoroughly before discarding in trash.</u>
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. <u>Do not incinerate or puncture.</u>

2. All other products must bear container disposal instructions, based on container type, listed below:

<u>Container Type</u>	<u>Statement</u>
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused <sup>1/</sup> , dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

<sup>1/</sup> Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

### III. BIBLIOGRAPHY APPENDICES



## Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

- a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

- b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.
- c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."
  - (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.
  - (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.
  - (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION STANDARD BIBLIOGRAPHY  
Citations Considered to be Part of the Data Base Supporting  
Registrations Under the Diazinon Standard

<u>MRID</u>	<u>Citation</u>
00020560	Schafer, E.W. (1972) The acute oral toxicity of 369 pesticidal, pharmaceutical and other chemicals to wild birds. Toxicology and Applied Pharmacology 21(? ):315-330. (Also in unpublished submission received Apr 25, 1978 under 476-2180; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233577-C)
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V. FORMS APPENDICES

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET		EPA REGISTRATION NO
PRODUCT NAME		
APPLICANT'S NAME		DATE GUIDANCE DOCUMENT ISSUED
With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner.		
<input type="checkbox"/> 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:  Attach separate page with a list of the data requirements your company agrees to satisfy.		
<input type="checkbox"/> 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:		
NAME OF OTHER REGISTRANT  Attach list of data requirements		
<input type="checkbox"/> 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements		
<input type="checkbox"/> 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):		
<input type="checkbox"/> 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)		
REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

<b>CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA</b>		
<i>(To qualify, certify ALL four items)</i>		
1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:	GUIDANCE DOCUMENT DATE	
	ACTIVE INGREDIENT	
NAME OF FIRM	EPA COMPANY NUMBER	
(This firm or group of firms is referred to below as "my firm".)		
2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:		
3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):		
NAME OF FIRM	DATE OF OFFER	
However, none of those firm(s) accepted my offer.		
4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.		
TYPED NAME	SIGNATURE	DATE

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No. \_\_\_\_\_ Date \_\_\_\_\_

Guidance Document for \_\_\_\_\_

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	Submit- ting Data (At- tached)	(For EPA Use Only) Accession Numbers Assigned
Subpart C PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk- density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

PRODUCT SPECIFIC DATA REPORT (cont'd)

EPA Reg. No. \_\_\_\_\_ Date \_\_\_\_\_

Guidance Document for \_\_\_\_\_

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submit- ting Data (At- tached)	
Subpart C PRODUCT CHEMISTRY (cont'd)					
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explosibility				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric break- down voltage				
Sec. 158.340 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitiza- tion,				
81-7	Acute Delayed neurotoxicity, hen				

EPA Form 8580-4 (cont'd)

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: \_\_\_\_\_

Registrant's Name and Address: \_\_\_\_\_  
\_\_\_\_\_

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated \_\_\_\_\_ concerning a requirement for submission of "generic" data on the active ingredient \_\_\_\_\_ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated \_\_\_\_\_ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are \_\_\_\_\_ and their registration number(s) is/are \_\_\_\_\_.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: \_\_\_\_\_  
(Signature)

Dated: \_\_\_\_\_  
(Typed)